Vocabulary Task Force
Draft Transcript
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Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. We just introduced the members of the committee around the table, and I believe we have a number on the telephone. Bob Davis, are you there for Don Bechtel?

Bob Davis – Siemens Medical
I am here for Don Bechtel.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Thank you. Anybody else on the telephone? All right. With that, I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thanks, Judy. Welcome, everybody, to this session of the vocabulary taskforce, established under the Health IT Standards Committee. Just for context, the Health IT Standards Committee is a federal advisory committee charged with recommending standards and certification criteria to the National Coordinator. Within that standards committee, the clinical operations workgroup is charged with recommending standards for content exchange and vocabulary, and this vocabulary taskforce was formed under clinical operations to bring a broader group of experts in controlled vocabularies to bear on questions related to meaningful use.

Within our initial focus on meaningful use, we're here today to better understand how to enable implementers of EHR technology to effectively use vocabulary standards. We're doing this in a program that we've established under the taskforce, first focusing on questions of governance, of vocabularies specifically for value sets and subsets of the controlled vocabularies. Next, after this group of sessions, we plan to focus on questions of infrastructure and tooling. And then, after that, we'll move to other coordination efforts that are needed to more effectively enable implementers of EHR technology to effectively make use of the vocabulary standards.

This is the second in a series of two hearings that we're having on governance of value sets and subsets of vocabularies. In the first hearing last month, we heard from the EHR vendor community. We heard from service providers, vocabulary service providers and from messaging standards development organizations. Today we're hearing from the Office of the National Coordinator, from government providers of care, and government agencies with experience in controlled vocabularies.

The questions that we're here to address today specifically are around who should do what and what is needed for effective governance of value sets and subsets, again with the focus on enabling meaningful use. Then, secondly, we're here to address the question of what should be the role of the federal government in managing value sets and subsets for meaningful use. So within that context then, I'd like to turn it over to Betsy to review what we heard in our hearing last month.

Betsy Humphreys – National Library of Medicine – Deputy Director
Thank you, Jamie. On February 23rd, we heard a lot of very interesting input, which was varied, but we did hear certain things more than one time, and there seemed to be a degree of convergence around the

notion of the government's role in terms of providing a single, central authority to govern processes, to sort of set them up and manage them, and make sure they went forward. The processes to be opened so that people could, in fact, contribute; anyone who was interested could contribute to this. So the notion would be that the government would have a single, central authority that would be managing selection and harmonization, updating of controlled vocabularies and key subsets, providing standards and probably an infrastructure, but maybe not an infrastructure for value set creation and maintenance, clear delegation of authority, and responsibility for particular value sets. The notion that there probably would be multiple groups involved in having responsibility for particular value sets.

Types of organizations mentioned were standards development organizations in terms of value sets required within their messaging standards, for example, and certain government bodies like CDC and others that have special responsibilities for particular use cases and areas. That, in effect, the authority should be in a position to harmonize or set up a process that would truly harmonize value sets across use cases when, in fact, the same value set really applied to multiple use cases and was used in multiple standards, and that the organization or the authority should have basically the ability to make the SDOs move in response to decisions made in this area.

And that the authorities should also be setting up standards for and dissemination mechanisms for people to get access to all of this, and we heard a range of opinions about what that should be. Everybody thought there should be a very usable infrastructure for getting these. Some felt that decentralized would be better, or some said centralized, and there were multiple formats mentioned in terms of distribution leading to this not surprising conclusion that you probably want to disseminate these things in multiple formats for different types of use and users, and that there should also be some attention paid here to having sufficient education guidance, frequently asked questions, and so forth for the people who have to implement these.

The other key pieces of advice or comments were just the truth that the ongoing maintenance is essential for vocabularies for subsets that are generally used, and for value sets, and that this requires a real organizational commitment and resources over the long haul. That value sets have to be bound to their context with the direct involvement in their production of those who actually really understand the context, that is, the use case, the model, the message, that they can't be developed sensibly separately from the context in which they will be used.

There was a recommendation that the government proceed to remove licensing barriers, access barriers for other key resources in this space with the SNOMED CT cited as a model of what might happen. And then there was a clear, strong statement that things had to be easy for implementers to define things, to use them, to get guidance on everything that they needed for meaningful use. And that this needed to be in some centralized place where you could find out what everything was and where it was and how to get it.

Then on the notion of convenient subsets, perhaps a more minor point than those that went before, we heard that the government supported frequency based subsets where useful, that is, based on real use statistics across multiple organizations that covered the spectrum of care, and we sort of heard from more than one testifier that we could just leave any specialty set creation to vendors or societies and not spend too much government effort on those. Although, again, the notion that there might be standards for how these were generated in a central place to find out what existed and how to get them was of interest to multiple testifiers, so that doesn't give you the whole rich feeling of all the excellent points that were made, but those were some of the ones we heard more than one time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Betsy, thanks very much. Let me just ask the members of the taskforce for other observations from last month's meeting, things that you recall or additional points that you wanted to emphasize in terms of the summary. Is there anything? Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I agree with every point Betsy has summarized. I would add, however, that I think there was an undercurrent of opinion that canonical value sets, that is to say, value sets assigned for a specific purpose really need to be realized, and the authority to designate them evolved.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Thank you. I would say there was also some discussion in, I believe, a couple of the panels about designating canonical value sets by use case, and then a need for harmonization of value sets across use cases, as perhaps a separate process. And so that was something that was, I think, discussed in the context of being facilitated by the central authority, but not actually done by that authority. Stuart?

Stuart Nelson – NLM – Head, Medical Subject Headings Section
I'm sorry that I was not able to attend the last meeting, so I have two sets of questions. The first questions relate to the licensing issues. Was there any sort of consensus about what is a reasonable license?

Betsy Humphreys – National Library of Medicine – Deputy Director
I would say that it was more in the neighborhood of solve this problem. I mean, the comments that we heard, I mean, obviously if we had asked people, we might have gotten some interesting opinions. But in terms of what was said during that, it was sort of like solve this problem, and two particular issues that were, I mean, two that were mentioned at least in written comments that I reviewed recently, HL7 and CPT.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
Because the reason I ask that question is I've just been having some offline discussions with some other people in the bioinformatics who view any license agreement that requires them to sign as a great imposition on the forward progress of science, and so there is that opinion that's floating out there. The other question I had related to the creation of these convenience subset value sets, and it seems to me that if every group develops their own little special value set, that the ultimate goal, at least in my opinion, of achieving interoperable records may be defeated because everybody is just talking to their one little special group and not really enabling comparable data across multiple institutions.

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes. I think there was actually a huge amount of enthusiasm for these, although people felt that they could perhaps be useful in terms of specializing data entry for particular specialties, not that they would be the only subset used, but they might be the ones that were featured and so forth. There really wasn't a lot of, you know, enthusiasm around that concept.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think, also related to that, I'll say that in discussions of our parent committee, the HIT Standards Committee, there have been, I think, primarily two points of view discussed as alternatives for how to make these convenient subsets available for starter sets for new implementers of EHR technology. One is that a frequency distribution of the general purpose use of the whole vocabulary, the entire frequency distribution should be made public. Then each implementer can choose essentially their cutoff point or their subset, but do it based on that entire frequency distribution.

Another point of view is that an initial subset, a base level of minimum subset should be established just, for example, the top 95% of routine lab tests ordered that are reported in HEDIS is an example that's used frequently for a defined subset as a starter set, essentially based on a frequency distribution concept, but it's sort of providing a convenient subset versus providing the entire frequency distribution. I don't think there's any particular consensus on one versus the other at this point in time.

Welcome, Marc. Thank you for joining us here. Just to note that Marc Overhage has joined us here.

Is there any other discussion on the hearing from last month? Okay. Hearing none, I think we're ready to proceed with our first panel. Doug Fridsma from ONC?

Doug Fridsma – ONC

Thank you, Jamie and committee, for the opportunity to sort of talk to you a little bit about some of the work that we're doing in the Office of the National Coordinator. Work that has been going on for a couple of months now, which seems like forever, but actually it's pretty fast. And I wanted to sort of get some feedback, to give some awareness of some of the efforts that we have in the office, particularly as it relates to some of the key points that you've just articulated about sort of the role of government and what we should be doing. Can we start with the first slide?

What I'd like to spend a few moments talking about is what I've been calling an interoperability framework, and this is an effort to help integrate and manage some of the implementation specifications that we are legislatively mandated within the office to produce, as well as managing sort of the standards harmonization processes that we have as well. There are a series of competitive contracts that we are obligated to put out there that will continue a lot of the work that has happened previously through HITSP and through some of those other organizations. And so this is, the interoperability framework is really our effort to start to integrate and provide some framework for how we get from use case development all the way to certification criteria.

When we were thinking about what we needed to do to support standards and interoperability and data exchange within the HITECH Act and our legislative mandates, one of the things that we quickly realized is that we needed to move towards more computational implementation specifications. And so, there has been previous work on taking standards around use cases and developing implementation specifications that tended to be human readable with Word documents, but not necessarily have a lot of the kind of ability to have computational artifacts. If we're going to be able to manage this, we felt we needed to try to have more computational artifacts, so that we could scale the processes, develop tools against it, so that we could do it more efficiently, and that the closer we got to something that a computer could read, the less open to interpretation it might be, and the more likely we're going to get interoperability based on those specifications, so that was one of the first things that we wanted to take a look at.

The second is that the Office is responsible for making sure that the meaningful use, use cases, as defined by the HIT Policy Committee, can be driven essentially through the HIT Standards committee, through to implementation specifications, and onto certification. And we needed to be able to make sure that those pieces all fit together. And so we wanted to make sure that there weren't silos, and that we had some integration across all of those activities so that the things that we get for guidance from the policy committee really get translated into the technology, the standards, implementation guides, and the certification criteria.

Finally, we wanted to be able to do this and interact with all of the standards development organizations that were out there that are mentioned in the IFR that defined things like what's the transport that we need. What is the vocabulary? What are the value sets? What are sort of the security implications?

And that we needed to find a way to coordinate, not so much that we would be developing standards, but that we wanted to make sure that the standards that were out there that got kind of integrated together to support the goals of meaningful use, a policy committee, and standards.

In many ways, this is just a continuation of the work that has gone on previously. HITSP has been doing a tremendous job harmonizing and integrating standards. They focused on developing some implementation specifications, identifying gaps. We recognize that we need public/private partnerships, participation of SDOs, and integration across HHS. The recently passed healthcare reform bill actually indicates that there are some areas in which there needs to be integration for administrative simplification, standards around kind of supporting that within health and human services. And we wanted to make sure that whatever we do, we can create some sort of integration across all of those activities as well.

I know many of you are familiar with NHIN Direct and a project right now that's working on developing some new specifications and broadening the participation in the nationwide health information network. We actually want to use that project as a pilot of testing some of the ideas that we have with this interoperability framework.

Finally, one of the challenges that we have is that we can do this top down, in a sense, sort of a command and control, which helps us get to the end goal, but really, I think, limits the kind of broad participation that we'd like to see in the development processes. Or what we can do is we can sort of let a thousand flowers bloom and let lots of people do important and interesting things, but not necessarily have the kind of coordination that we want. And so what we're really hoping to be able to do is to thread the line between those so that we have focused collaboration in which we can get transparency, engagement, rapid results, can create priorities, and to sort of focus on what needs to be done to help us meet the goals of meaningful use, as well as the goals of integration across health and human services, but to do it in a way that is open, collaborative, transparent, has good governance, and can engage lots of people who have things that they contribute.

Here's the interoperability framework. Any questions?

I'm going to step through each of these boxes here that sort of describe the processes that we're talking about, and so we'll have an opportunity to sort of take a look at each of these pieces and kind of how it relates to both current activities and where we'd like to go. The first is that we need to have use case development and identify functional requirements. One of the examples of a use case might be that a provider wants to send a referral to a specialist electronically. What we want in that particular use case is we want to describe the services, sort of what are the functions that need to be accomplished; the standards, what's the package that needs to be sent perhaps from the provider to the specialist; and something about the business rules, trust, policies, and other things; all of the things that are necessary to satisfy the particular use case.

What we want is this process to engage a wide community that can define those use cases and focus on solving a real problem. Part of the reason for focusing on a real problem is that we can then test whether the use case solves that problem. If we model in the abstract, then what we end up is sort of an analysis/paralysis. We never can quite get to know whether we've accomplished what we intended to do.

And to try to do this in a transparent way, very similar to sort of what HITSP has done in the past. We also want to try to establish what we're referring to as a use case steward who will shepard the use case through the entire process so that there's a stakeholder who makes sure that whatever gets defined in terms of the use case actually looks at the standards, the implementation specifications, the reference

implementation, and certification criteria so that horizontally we've got a lot; we've got that kind of coordination.

Generally, the person or organization that brings the use case to us or to this particular framework would be the group that would sort of shepard that. So if it was something that came from, say, the VA or the DoD, or as part of VLER or one of those things, there would be someone identified that could help do that. And the goal is that at the end of the description of the use case, we have a clear description that is in something that is beginning to look computable that describes the standards, services, and policies necessary for that particular use case.

The second step, and this is where we'll probably spend a fair amount of discussion at the end is harmonization. Again, going back to that notion about whether we want to have a thousand flowers blooming, or whether we want to have sort of kind of command and control, what we really need to have is we need to have a mechanism that allows multiple use cases that may have overlapping standards, services, and policies to be able to harmonize and at least agree upon some commonalities across those use cases. So I've described a couple here. These are just examples. These aren't things that we have necessarily in the queue, but you can imagine that an e-prescribing use case and an adverse event reporting use case may have overlap in terms of the way in which descriptions of medications and reactions to medications would be described.

Certainly a clinical care summary and quality reporting have overlaps so that we would like to be able to use summaries of clinical care, aggregate those things together, and be able to provide quality reporting. And things like laboratory data exchange and clinical decision support, one could argue that there are certain decision support rules that would need to fire or need to be able to be driven by laboratory values, and we want to make sure that there's consistency across those.

To do that, we need to have a strong harmonization framework that spans different standards organizations and that allows us to kind of create XML or UML descriptions of use cases and allow sort of that use case driven bottom up approach to have top/down coordination, so that we get some harmonization across that. It's going to require some strong governance and some transparency in the processes. And, at the end of the day, we'd like to be able to come up with descriptions of standards, services, and policies that are standardized in some way, and allow us to describe similar things in similar ways so that they can be used for different kinds of use cases.

The three parts to harmonization, again, are going to be, and I'm going to kind of keep harping on this because I think it's critical to the way in which we want to be able to describe this. Those of you who are familiar with NHIN will probably see that when we talk about that, we talk about oftentimes services, standards, and policies. In a sense, those are the three components that we've got even within this harmonization program or project.

Three parts to harmonization, one includes description of the standards, the package or the data that's to be exchanged. A second would be a description of the services, which are the functions that need to be supported in the exchange. And a third would be descriptions of the policies, which are the trust relationships, business rules, things like that. And so we need to be able to describe all three of those things.

With regard to kind of the data package, we want to leverage some of the best practices that have been used, both in state, local, and federal government. We've looked at the NIEM process, which is the National Information Exchange Model, as a model that is used across the federal government and within HHS right now to support child and family services, as being one of the approaches that we can use to

get the data and exchange packages right. And from that harmonization, we want to create explicit data exchange packages that describe data elements, vocabularies, and value sets, and drive down to the level at which we can really describe what's necessary for exchanging that information.

Now the NIEM process focuses primarily on the data, but we need to have some additional functionality if we're really going to be able to get interoperability, as we've described. What that means is we also have to have consistent ways of describing services. And so one of the initiatives that both HL7 and the NCI have described is something called SAIF, which stands for Services Aware Enterprise Framework. I think I got that right, and I can – did I get it wrong?

W
It's interoperability framework.

Doug Fridsma – ONC
Interoperability framework. I'm sorry. There's an "I" in there someplace. And what SAIF does is it really has sort of four different models that come out. One is called the information model. The second is a service description that describes behaviors. There's a conformance model that talks about kind of conformance testing, and the third is a governance, which really is sort of the business rules around that. And we need to be able to describe services as well to include that in our ability to get to sort of harmonized standards. Finally, we need to have policy descriptions, and I think harmonization of policies is a challenge, and I'm not sure that we have that figured out. But clearly that's something else that needs to be included when we talk about implementation of these standards, so a lot of questions about what the NIEM process is.

It stands for the National Information Exchange Model. It started as a Department of Justice initiative, but it's a process that has been generalized beyond that. It's supported data integration and reporting for recovery.gov. It's used by HHS right now to support child and family services. It's been recommended by the Office of Management and Budget as a best practice, and it's currently being used by state and local governments to help support data interchange within those organizations as well.

What NIEM really does, it defines a common core of concepts that are explicitly defined and that are shared across different use cases or domains. And so you can imagine that you have things like laboratory data exchange, provider address lookup, a discharge summary, maybe patient summary, child and family services that all have common descriptions of things that they have that they've shared. NIEM uses a naming and modeling convention that allows different groups to work independently, but then be able to harmonize that work together. Fundamentally, for those geeks in the room, it's based on the ISO 11179 metadata standard that's been used by the NCI, NLM, and other standards organizations, so there is some framework underneath here that sort of makes sense.

One of the things that they also have within the NIEM process is tooling right now that exists to help with the information exchange modeling, to help support mapping and browsing through the model. There's some schema, subset generation, and some information packaged documentation tools that are accessible as well. And so it does provide at least a starting point for developing some tools that may be able to support this process because, at the end of the day, we need to make this not something that is manually kind of hand crafted, but if we're going to be able to both develop, maintain, and support implementation specifications, we need to have tools that will allow us to do that efficiently and get to the point where, you know, people can start doing this themselves.

One of the things that the NIEM folks have done a good job at is taking a look at cost and whether or not they can save resources by using this. This is just an example of some of the estimations that they did

around recovery.gov, looking at using the NIEM process versus creating customized XML interfaces and what the savings might potentially be on this. So it's an estimate. It's not something that you can do the experiment.

They didn't go and try to generate custom XML interfaces. But they spent approximately $4.8 million to develop 3 exchanges that were used across 100 different systems to report data. And, estimated, had they done that with a series of customer XML interfaces, it might have cost them upwards of $17.5 million. I can go through kind of the model that they used to generate this, but they really felt as if they could save a substantial amount of money by having a common framework in which to develop these things. I think what's more important as well is that 8 months after the HITECH Act was signed through the ARRA stimulus money, that there were over 100,000 recipients across 50 states, 200 federal programs, and 22 agencies that were successfully reporting information to recovery.gov as part of the NIEM process.

The other thing is that, as we go through this process, we anticipate that there are going to be gaps that we identify. There may be gaps in existing standards around the data packages, value sets, services, and that will be identified, as we go through the use case development and harmonization processes. So there's going to be an important work to work with standards development organizations, National Library of Medicine, HL7, and others to help fill in those gaps. This is really not a standards development process or framework, and so we really have to rely on the standards development organizations to help us with that. And that we can allow the standards work to proceed in parallel with development of the implementation specifications, particularly if we want to have sort of draft specifications that later can get filled in.

One of the important targets really is going to be the implementation specifications that conform to the adopted standards that the Secretary has, and are sufficiently detailed to be implemented. The way I like to describe this is if the standards, services, and policies are the ingredients, the implementation specification is the recipe for how those things come together to bake the cake, which might be the code that you're going to be using. Packaged together to support the use cases, the implementation guides really are going to guide the development of reference implementation. And so the interim final rule requires the creation of implementation specifications where, in some sense, they currently don't exist, and we need to be able to support that.

Our office right now is working very hard to do the crosswalk between the meaningful use requirements, the standards that were adopted by the Secretary, and where the implementation specifications are and where they aren't, so that we can kind of begin to fill in those blanks because that is something that we need to do as part of the legislative mandate. A reference implementation is really the cake that gets baked as part of using the recipe, if you will. An example of that is that the Connex offer that the Federal Health Architecture, FHA, has developed, could potentially be a reference implementation of some of the specifications, for example, that the Nationwide Health Information Network uses.

Part of the reason that this is important is that we can't develop specifications in the abstract. We need to actually make sure that they're implementable and that people can actually build reference implementations to them. The thing that's different, of course, is that if you build a reference implementation, and you find that there's a flaw in your specification, you have to go back and fix it. And so, it isn't that you tweak the reference implementation so that you can develop something that people can use. You actually go back, and you have to change your recipe, if you will. And I think that's a critical piece that we have to have in this process because if we don't actually build those things, we run the risk of development implementation specifications that don't really serve our needs that we think sound good on paper, but in fact when you actually build them, they don't work.

Pilot demonstrations is sort of a next step is that if you have a reference implementation, people should be able to use that and actually develop those within their own organization. It's sort of the difference between doing a phase three clinical trial on a drug that says, we think the drug works, and we've done that, and actually getting it out there in the marketplace and seeing if people actually can use it, and if there are other unintended side effects of the technologies that you have. And so we want to be able to support pilot demonstrations as well, and so we've done some work in the past with NHIN around trial implementations.

We've got a project now with NHIN Direct that's trying to develop specifications. Remember, I said that NHIN Direct was a project that we want to use to test this framework, and so we've got a group that's developing use cases. We want them to develop the services, data, and policies that we need, come up with an implementation specification that can be used as a reference implementation, and test it out there in the real world. And we're going to try to do this on a relatively short timeframe.

Finally, a lot of the work that we're going to be doing has to lead to certification and testing. And so we want to involve NIST and some of the other folks that will help us create some of the testing. They're going to help develop. NIST is not going to be doing the testing per se, but they're going to help develop sort of conformance specifications and things like that, that certification bodies can use. We want to make sure that we don't develop implementation specifications that can't be tested, and that's another issue that can sometimes be a challenge. And so, throughout this process, we want to have participants from NIST involved so that we actually create implementation specifications that can be tested so that we can do the next stage that we need to have with this.

Finally, the only way that we're going to make this scaleable and sort of allow us to move forward is to make sure that we can make this as automated and self-serve as possible. And so, throughout this process, we need to identify tools and services that can help leverage this work and make it possible that use case development actually can reuse some of the components that are already there, and that we have mechanisms for people to be able to access the implementation specifications, the data descriptions, the service descriptions, and the policies, and be able to incorporate those into new use cases and new things that they might want to do. And so, we hope to be able to support this entire process with some tools and services that will make this easier for people to engage with this as well.

In many sense, what we want to do is we want to create something that allows for bottom up innovation, driven by use cases, but within a coordinated framework that allows us to sort of move from descriptions of use cases, and get to the point where we have testable implementations and testable specifications that we can use for certification as well. And, to be able to use this, quite frankly, to not only help us with meaningful use, but to make sure that we do it in a way that allows us to think more broadly, particularly with the new health reform bill, some of the obligations that we have around standards, and to make sure that we can support health and human services across the agency. With that, I'm going to stop, and I'm sure that there'll be lots of questions, but I'll leave this slide up because it has sort of a summary of all the different things that are going on.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thanks, Doug. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you, Doug, and I want to compliment you on what is obviously a very thoughtful and carefully considered presentation and framework. I know many have worked on this. I want to raise two issues. One, if you will, is a more rhetorical comment, and the other is a genuine question.

The rhetorical comment is, I and others are very much aware of the time constraints that were involved in the recent RFAs that essentially require the use of the NIEM infrastructure as a prerequisite for response to development much of what you describe here. The rhetorical comment really surrounds a bemoaning that there was no opportunity, either within the standards community or any committees to discuss the relative merits of NIEM. NIEM may in fact be an excellent framework, but it's clear that, as my colleague, Dr. Overhage, reminds me, with healthcare being nearly 20% of the economy and probably with more effort and experiment and body of work in the domain of interoperability problems, it begs the question of which is the tail and which is the dog as far as defining what an overarching framework should be.

The more useful question, I guess, is despite the fact that NIEM has model in the name, for those of us that have examined it somewhat carefully, it appears not to be a model driven framework at all. And, in fact, makes itself potentially to be faulted from setting up and establishing independent silos of interoperability, granted sharing common syntax. But not necessarily sharing a common, conceptual framework of coherency. I recognize that this is both a disadvantage and potentially an opportunity. But I guess the question is, how do you see this NIEM framework, as healthcare begins to embrace it, actually achieving the kind of coherent integration across structures that I think we all seek?

Doug Fridsma – ONC
Thanks. I'll just comment on your bemoaning. I think, within the office, our desire is to be as sort of open as we can with all of the things that are going on, and I agree. I think having an opportunity to talk more about this would have been advantageous, but given the constraints, we did sort of the best that we could. I think, as well, the federal advisory committees were very focused on kind of responding to meaningful use, once the regulations came out, and it became hard to sort of be able to get on agendas and things like that. But I hope that we will have an opportunity now to begin sort of talking about this as well.

With regard to your second comment regarding no particular underlying sort of semantic model within NIEM, the NIEM process is one that I think provides us a good starting point, but I don't think it's necessarily the end. I think we've recognized that even those people that are very supportive of NIEM recognize we don't have service or behavioral kinds of descriptions, and that needs to be included. I think that when it comes to the semantics, there are lots of places that we could push that.

I mean, you can have semantics in your value sets. You can have it in external anthologies that sort of support the process. You can have it as part of, as HL7 has it, as part of the RIM that provides a context for that. I don't believe that there's anything inherent within the NIEM process that would prevent developing some sort of underlying model or semantic framework that could be supported within that, and I would hope that as we move forward, since semantics is something near and dear to my heart, and certainly something I think that will be important for supporting future use cases that we have, that that may be one of the things that we take a look at very early on to see if that's something that can be extended, as part of that process as well.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Marc?

Marc Overhage – Regenstrief – Director
Not having studied NIEM at all, I can be very ignorant. It'd help me, and I think Marjorie was saying, where's the *NIEM For Dummies* tutorial. I needed that. I think it would help me, and perhaps others, to hear, so we have a set of terminologies, we have a set of transport protocols that are specified in the now final rule. We have a set of message structures. I'm a little unclear about how NIEM and, in particular,

the XML representations that are part of its product in my little bit of reading about it. I don't understand how those fit together, and so that picture would be really helpful. Then I have a second question, but I'll get that one first.

Doug Fridsma – ONC
Sure. Part of the NIEM process involves creating sort of a governance structure that helps with priorities and kind of the work that needs to happen. It requires integration of existing value sets, vocabularies, terminologies, again focused on those particular use cases, and describing in some fashion the data that's required, the services that are required as well. And so, much of the kinds of models that NIEM generates are UML models that describe those services and behaviors, that describe the data packages as well.

I think when it comes right down to it, what we want it to be able to do, and one of the reasons that we looked at NIEM, in addition to sort of being asked to by the Office of Management and Budget, is we wanted to make sure that we have a framework that would allow us to get to sort of a computational view of this. Now how, I have another slide that I don't have in this stack that really talks about, again, one level down in terms of the coordination operationally about how we might do this. That may involve things like how do we integrate things like lex grid or EDS, vocabulary and terminology services into this particular process. How do we come up with a service registry that is not something that's currently part of the NIEM process, but likely will need to be extended to be able to support those kinds of descriptions? And how do we sort of create the XML or UML descriptors of the exchange package?

I would like very much if we got to the point where an implementation specification was essentially a computable artifact in XML or UML or whatever it was with an executive summary that allowed human readable interfaces that says, I know exactly what the use case is. I know exactly what this is trying to do. I know what standards have been referenced, where it is, all of those things. As opposed to sort of the other way around, which is, large, human readable documents with references to the XML or the standards and stuff, so we're trying to kind of change this a little bit.

Marc Overhage – Regenstrief – Director
If I may, I understand the aspiration to create computable implementation guides. If you can bear with me one more level, and that is, so HL7 version 3 strives to be a computable representation, so is the NIEM process a replacement for HL7 version 3, or how does it fit?

Doug Fridsma – ONC
No, I don't think that it's a replacement for that. I think, as you know, with the standards that were adopted by the Secretary, there were a large number of HL7 standards that were adopted. But there are other standards as well that were kind of outside the purview of HL7 that were adopted as well. There are some administrative transactions. There were other standards for sort of the patient care summary. There were standards around e-prescribing that were different. And so all of those different standards and packages need to have some mechanism to be harmonized so that th data and the semantics that are described in the CDA for, say, a patient care summary is consistent with at least other things that would be relevant in, say, the X12 and some of the administrative functions.

And that would be true, as well, if we were talking about e-prescribing and drugs. We need to have a mechanism to make sure that those are the case. In fact, I don't believe that the SDOs are irrelevant here. In fact, they need to be a central player and part of this process. The problem was that there needs to be a place that they all can kind of come together, and we can kind of figure out what are the relationships between them.

Marc Overhage – Regenstrief – Director
So highly relevant to the rest of the day's discussion – why do they have to all come together? Frankly, a lot of it is in the transactions that happen with administrative functionalities happen with a certain group of participants. The e-prescribing applications happen with a different group quite successfully, I think it's fair to say. Why do they have to all come together?

Doug Fridsma – ONC
I could ask someone else. I could ask others to answer that question. You know, the issue would be is if we don't believe that within those different silos of use cases, that there is no semantic overlap, and there is no need to reuse them. You're absolutely right. They wouldn't need to come together. We could have different kinds of descriptions of those things. And it would seem to me though that if we want to have the ability to reuse some of those semantics across the different ones, we're going to have to figure out some way to either create mapping, and then we worry about sort of the N-squared problem, if we have to map between all sorts of different use cases, or we come up with some way that says there are some use cases that overlap, and let's see if we can gain some efficiencies by trying to do it. You know, define once, use many, as opposed to define many and map between many. And I think that was sort of the hypothesis that this would potentially support.

Marc Overhage – Regenstrief – Director
I'll be quiet after this, but I guess the key struggle that I have, and those are all laudable goals, of course. I think those are all good things to happen. My concern, I guess, as I hear this, is it's sort of like going back to square one on a lot of this work, and even in the use case. Talking about starting over with use cases makes me anxious about where the market is in terms of an ability to adopt and move forward in these areas if we're going to go back and revisit. All good things to do, and so I guess maybe where I'm coming from is, is that the most – it's a good thing to do. Is it the most important thing to do at this moment in time to make progress? I think that's my fundamental struggle, as I try to think through this, so thanks for the explanation and making me just a little bit smarter. Some day I'll catch up with Chris. No, it probably won't happen.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Stan has a question next, but I'd like to follow up on Marc's first question, I think, which has to do with, I think, your description and what your slide show is about NIEM producing the XML artifacts, and that is that in fact one of the things that NIEM does is to produce the detailed implementation specifications. In fact, there are detailed implementation specifications that exist that are already adopted and recognized standards for the use cases that are in meaningful use, so what's the relationship of this new creation of these new implementation specifications to the existing adopted standards that are in production around the country.

Doug Fridsma – ONC
We've had some experience with the C32, which was a HITSP standard that had an implementation specification associated with it. And there have been challenges within the VLER project and some others in trying to get interoperability even using the C32 because there are optionality and choices that sometimes aren't clear in those specifications. And so, even with existing implementation specifications that are out there, there are some challenges that we have.

I think one of the things that we are looking at right now is, we could continue to maintain implementation specifications for the variety of different specifications that the secretary has adopted in the IFR. And we could sort of maintain kind of separate, but equal, when it comes to those particular specifications. I think, certainly in the short-term, that's probably all we have available to us to be able to do that. But I

think, ultimately, what is hoped is that we provide a mechanism in which there is some reuse of these sorts of things.

To Marc's point, the goal here is not to start with a blank sheet of paper with the existing use cases and start over. We have a tremendous amount of work out there that is all good, and some of it is in Word documents that have links to standards, and some of it is in UML diagrams, and some of it is in different formalisms within HL7 that has sort of a different way to describe those things. I mean, semantics are the same; the representations are different. It becomes hard then to be able to do that kind of harmonization because you don't have a common framework. You can't build tools against it.

And so, I think part of the goal here is to see, at least on those that we think are high value, can we backfill existing work with HITSP that could help jumpstart this process? Clearly one of the things that's happening within NHIN across the exchange is to make sure that the Connex software is interoperable with the specifications that are going to come out of the NHIN Direct project. How do we do that? We could create two parallel activities, and we could merge them together, or we can try to backfill those specifications and make those accessible to the folks that are going to be doing the NHIN Direct project as well. That's sort of one of the things that we're working on.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Stan is next, and then it looks like Marc has another question.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
It's occurred to me, and I'm sure others, and I think it's common motivation for what the process you've drawn here is that, you know, having been around for a while.

Doug Fridsma – ONC
You or me?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
You can ask the question and say, isn't there an underlying commonality of framework capabilities across all of the standards? Why is it that we're doing vertical bar stuff one place, and we're doing EDIFACT in other place, and that's not the real value added of what we're trying to do. It's the semantics and the connection to real world business and clinical care processes that we're trying to do.

I find part of this very persuasive that says, you know, and you haven't mentioned it, but it really starts with data types. What are the fundamental data types that we use as building blocks that then build into bigger information models that tie to value sets and terminologies and that represent a logical structure of information that's exchanged, and then turning those into APIs and service interfaces that we can actually implement. That, to me, is incredibly persuasive and very laudable. Then that's a natural fit, in a sense, because you need – once you have that infrastructure in place, you need people who are experts in retail pharmacy or in clinical laboratory data exchange or image exchange or device interfaces. So IEEE and HL7 and DICOM and NCPDP all have a very natural role as sort of the repository of experts in the field to do that work.

But I guess what I see as the real challenge is sort of getting from where we are to that, and what's the timeframe you're thinking about because if I were just guessing based on previous experience, unless we do something very different, this is two or three years before we see meaningful new standards that conform to this new, commonly agreed to, and what is the timeframe you're thinking of, and could you say more about the actual process? I mean, through the RFA process that you put in place, are you really thinking that you would convene representatives from NCPDP, HL7, etc. to get together and, using an

open consensus process, agree to data types, value sets, modeling framework, all of those? Say more about the vision of how you see this rolling out and the timeframe in which you think it might happen.

Doug Fridsma – ONC

I think part of this is an extension of the work that HITSP has already done. So the HITSP contract that ONC was supporting expired, I think, in February or March of this year. We were required to openly compete that, and so contracts have gone out to help continue that work. This isn't as if we're going to be starting from scratch, but in fact we want to continue that work.

We had to have an open and competitive process for how those contracts for those activities would be supported. This, in a sense, you know, the use case development and the functional requirements are really the kinds of functions that HITSP had done previously. If you think about the tiger teams and the work that was done just in the last year about kind of creating a more focused and harmonized set of specifications, that's really what that middle piece is all about as well, the harmonization piece.

Now we would like to drive this to get more computational artifacts with this and clear definitions. And the implementation specifications, we had a lot of work that was going on in a specification factory to help support the Nationwide Health Information Network and to support some of those implementation specifications within the Office. But those were all kind of three siloed activities, and a lot of the work there, even within the implementation, within the specification factory repeated some of the use case development because they had a lot of challenge with taking the specifications that HITSP had produced and operationalizing them so that they could incorporate them in the Connect tool. And so looking all of those sort of challenges that we had in the past, this is an effort to sort of at least eliminate some of those, if we could.

In terms of it's frame, I think you're absolutely right. If we started with a blank sheet o paper, it would take us two to three years to probably come up to speed on that, and that's one of the reasons why I think there's a certain amount of backfill that will need to happen based on the priorities that we have in meaningful use and the other use cases that we have. We need to take those existing good work and make sure that we've got sort of a consistent representation that allows us to sort of use the tools to help support the process.

I think, as well, making sure that we've got a process that's got good governance and that has had a track record and some expertise that people know on how to use it is also helpful in terms of jumpstarting the process within HHS. Already there's work that's going on in Child and Family Services, so that's another thing that I think will help us to accelerate that. And we need to, you know, move as quickly as we can to help support the legislatively mandates that we have within meaningful use as well.

I think what you suggest, though, is that this isn't something that necessarily begins and ends with meaningful use, but in fact if the focus is on making sure that our core concepts and our data types and all those other things are agreed upon, and we get those semantics right, I can envision that there would be implementation specifications that would have a SOAP interface. That's certainly what the IRF describes. There could be REST interfaces. There could be HL7 2.x interfaces. There could be V3 interfaces.

All of those things could be different ways that people could accomplish kind of the implementation of those, but the core concepts have already been sort of identified, and there's sort of a place that people can go back and refer to. It doesn't get you interoperability between those different implementations for free, but it does make your job a little bit easier, I think, with making sure that people understand the semantic pieces behind the different ways that people exchange information from a syntactic perspective.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
To follow up, if I could, I'm still not getting a clear picture of how you're going to convene this. You reference the HITSP process in some ways that are good and some ways are concerning, and the reason I say that is that HITSP, you know, started out adopting or presuming to adopt and create implementation guides on top of standards, and some would argue that it's migrated, in fact, to being a standards developer in its own right. And so, at one level, but at the people level, the other thing that happened is that, and I'm speaking mostly from the HL7 perspective, there were people who just didn't have bandwidth to both do HL7 and do HITSP, and so some of the very best and brightest people were not participating in HITSP just because of bandwidth capability.

And I see the same problem going forward if you start this new activity, and it's not clear how HL7 members participate directly, you're going to have that same ongoing problem of the experts trying to divide their time between HL7 processes and this new process. And so I don't see yet clearly what your vision is of how that will work so that we don't end up with competing activities, but really coordinated and integrated activities.

Doug Fridsma – ONC
Well, I think we're going to try to use this process to help support the NHIN Direct project and the implementation specifications that they're developing there. That's going to be one of our first forays into this. And I think, if we want to create a way of integrating across all of the various standards activities that include HL7, administrative transactions, and vocabulary terminologies, all of those pieces, Betsy had sort of summarized one of the recommendations or one of the discussion items that came out of the last meeting of this group, which was, the federal government should have some role in helping to coordinate across all of the various standards activities that are ongoing.

This, although not initially driven by that recommendation of a month ago, certainly I think is consistent with that, and we need to figure out how to do that better. But it seemed to me that this group was at least thinking about, well, what are the ways in which we can get better coordination across this. I don't know how to solve the bandwidth problem, and I think one of the challenges is HL7 and the RIM and V3 are complicated, and they're sometimes hard to understand for people coming in. If we could make that process easier, we could get more expertise within HL7 that then could help support this activity as well. We just have to figure out how can we distribute those resources that we've got so that people can participate.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Doug. I think Marc Overhage had another question.

Marc Overhage – Regenstrief – Director
Unless you need to move on.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, please.

Marc Overhage – Regenstrief – Director
And I'm still trying to wrap my head around some pieces of this. You were just talking about the NHIN Direct and using this as an example, and I'm trying to put that together with statements that and you and others from the Office have made recently that said that NHIN Direct is about a transport protocol. But it sounds like this process is not just about transport protocol.

Doug Fridsma – ONC
No. Remember, this process is going to extend NIEM, which focuses on data to include service descriptions. So part of the thing that's sort of untested, we haven't really tried before within this process is to integrate some of the safe methodologies and some of the service descriptions. So, in large part, that's one of the areas that they're going to focus on. And, in some sense, because there's not a lot of that description already, there's not a lot of legacy that we have to incorporate. But, you know, the process itself is to try to get use cases, and to harmonize those, and to have an open process to develop the specifications. And so the NHIN Direct project, since it's going to focus primarily on services, will allow us to take a look at that piece that will be the extension of the NIEM process.

Marc Overhage – Regenstrief – Director
So content will not be part of the NIEM process as part of NHIN Direct?

Doug Fridsma – ONC
Well, to be able to actually get the reference implementation, people are going to have to exchange content, but that's not the primary focus of the NHIN Direct project.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
If I could maybe ask a clarifying question for clarification, I think, Doug, you mentioned a number of times here the need for backfilling the existing implementation specifications for the use cases that, in many cases, perhaps would be used in Direct, as well as the NHIN. Can you tell us, what do you mean by backfilling? Can you give us a specific example of what that is and what you mean?

Doug Fridsma – ONC
In December, when we were first looking at the NIEM process to see whether or not it would support the kinds of activities that we anticipated, we actually got together a small team internally to take the existing HITSP specifications for C32 and see if we could represent those using the NIEM constructs, and just see what the issues might be with that. So we did that. It took us about four weeks to kind of come up with the models around the C32. We didn't drive it all the way down to all of the value set enumerations and things like that to formally develop a package. But we had a certain amount of comfort that it was possible to make those kinds of – take the C32 and actually represent it using the constructs that we had within the UML framework and the like. When I talk about backfill, I mean those sorts of things: take existing HITSP specifications and the Word documents, and see if we can create the computational artifacts associated with those.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So it's a new representation of exactly the same implementation specification?

Doug Fridsma – ONC
Right.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay.

Betsy Humphreys – National Library of Medicine – Deputy Director
In addition to that, Doug, I gathered from what you said, perhaps additional specification because doing it, you discover that maybe there's too much optionality in some cases.

Doug Fridsma – ONC

Right, and in part, to help solve that problem, that two different people looking at the HITSP C32 implementation guide, implementation specifications made slightly different choices and ended up having not entirely compatible interchange. So you're right, I think there will be additional specificity, and we will identify things that may need to be updated, changed, or improved with this.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. I think that was helpful. Other questions for Doug? Anything else to add? Thank you very much. I really, we really appreciate your time here today. What I'd like to do is I'd like to have perhaps a five-minute break before we come back with our next panel. Actually, I think it's 20 past the hour. Why don't we come back on schedule with our second panel at half past the hour? So it'll be a ten-minute break, please. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
If you could take your seats, please, we're ready to begin. Thank you. Take your seats, please.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. I think we're ready to get started again. Thank you all very much. Next, we have a panel of the federal provider organizations. We'll be hearing from the VA, the DoD, and the Indian Health Service here. And so I think, without further ado, Linda, I think you're up first.

Linda Fischetti – VHA – Chief Health Informatics Officer
Thank you so much, Jamie, and I'd like to thank both the chairs, as well as the members of the panel for the opportunity to be here today. My name is Linda Fischetti. I'm the chief health informatics officer for the Veterans Health Administration. VA is very pleased that you solicited our opinion. We were able to join you here today.

As you know, VA is a national healthcare provider for 5.5 million veterans. We have now going on about a 30-year history of having a comprehensive, electronic, health record system that's been implemented in all of our clinical environments. Within VA, if a patient moves from one point of care to another, then that information follows them and is available wherever they are seen. The opportunity as the Nationwide Health Information Network, of course, is that we will be able to, at the veteran's choice, allow that information to follow them when they're seen outside of the VA network.

We recognize the importance of this committee's deliberations because standard coded terminology within electronic health record systems and used for interoperability will provide the critical infrastructure necessary for the computable benefits that we all seek for our health IT systems. Said simply, national consensus and conformance on terminology, terminology subsets, and value sets to support meaningful use will accelerate the national ability to exchange information that has relevance and is meaningful in both the sending and receiving systems. When achieved, the benefits will enable smarter systems to support our needs to make comparisons within a longitudinal health record, improve clinical decision support, quality measurement, performance measurement, public health surveillance, and clinical research.

While we do recognize that the terms of subsets and value sets are used in various ways, we feel it necessary to make just a quick definitional reference here as to how I'm going to use the term value sets today. The distinction that I draw between vocabulary subsets and value sets: Vocabulary subsets are generally drawn from larger terminologies for use in a particular context such as allergy lists or problem lists. Organizations may further define a subset creating a value set for actual implementation to meet their own business needs.

For example, the National Library of Medicine creates a problem list, subset, which provides convenience and promotes interoperability. But then, for implementation purposes, we need to further define it by removing pediatric specific problems. We don't treat children. And adding other elements that are specific to our patient population, so something that would indicate Agent Orange exposure. For this example, VA might modify a vocabulary subset to create an internal value set.

In order to achieve the benefits of the meaningful use, VA anticipates the need for national meaningful use value sets. Envisions becoming a consumer of these externally created value sets, and we stand ready to join with the other federal health providers to help identify the governance and the technical infrastructure that will be needed to create and sustain national meaningful use value sets. Implementers of electronic health records are best suited to help create these implementable value sets.

Value sets should be produced in public, transparent, consensus-based standards organizations so that the public has adequate input and that work is freely available. This is also particularly of importance to a federal community in that we are constrained by the Office of Management and Budget through their circular A-119 that when we participate in standards organizations, it must be an open consensus environment. These open consensus organizations should have a mechanism to receive meaningful use value set proposals from subject matter experts such as professional organizations. Once created, a mechanism for publication for use by all impacted individuals and organizations should be assured through the same principles of public, transparent, consensus-based management.

Some of the best practices that are based on our experiences include producing and approving value sets that are well defined, circumscribed, and that directly address a discrete clinical or business need. For example, a high priority value set might describe a simple, universally understood set of clinical, allergy reactions or vital signs. Value sets that define abstract or ambiguous concepts such as patient problems or diagnoses are definitely more difficult. We have also found that due to the inevitable lags in deployment, static concepts such as gender and religion codes are easier to put into value sets than highly dynamic ones.

Most importantly, value sets provide the most utility and value where they have clear, immediate, and obvious clinical utility and relevance. Therefore, initial efforts should describe relatively small, relatively static, high clinical priority value sets that have high face value for clinicians, and I'm going to read that one sentence again because this is our main recommendation. Initial efforts should describe relatively small, relatively static, high clinical priority value sets that have high face value for clinicians.

Finally, we note the creation and deployment of value sets bring a high maintenance burden. The maintenance burden can be decreased through the creation of shared procedures, mechanisms, and tooling to support the creation, maintenance, and distribution of value sets. Value sets published and described using metadata schemes such as that used by AHRQ for HITSP are important to clearly describe and document HITSP data elements for implementers, and I believe Mike Fitz Maurice will be addressing this as well in his testimony later. Additional work must be done on metadata schemas specifically related to versioning and longitudinal management. Versioning is of great importance for the value set itself, as well as its constituent member concepts, the source vocabularies and any messages or documents to which the value set is tied for meaningful use.

We endorse the establishment of a governance structure and technical infrastructure for managing and publishing terminology, including value sets, health providers. Federal health providers have a great deal of experience that could assist in establishing requirements for a set of processes, repository registries for maintaining and distributing the value sets needed for meaningful use. And so those are our short

comments today. We will submit them so that they will be part of the deliberations of this committee, and thank you for the opportunity to speak today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Linda, thank you very much. I believe next up is Nancy Orvis.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Good morning. My name is Nancy Orvis. As the military health systems director for health standards participation and information management information technology integration in the Department of Defense for Health Affairs, I'm pleased to be here to address you and respond to questions about healthcare vocabularies, value sets, and subsets. The military health system is a unique partnership of educators, medical researchers, and healthcare providers and support personnel worldwide that make up global healthcare network within the Department of Defense. We provide cutting edge healthcare to more than 9.6 million beneficiaries worldwide from the battlefield to home front, and to humanitarian missions, as we just did in Haiti.

The MHS provides truly global healthcare, and we need international healthcare standards, as we work in every environment with this. We operate in austere environments, which are standalone, electronic health records, to where we go to caring for wounded, ill, and injured in transport, and in brick and mortar facilities where we focus on keeping the service members healthy, while providing for healthcare needs of their family members at home.

With our large organization, we need to be able to have timely access to the information that helps them make better decisions and enable better health outcomes. Our strategic plan is to provide the right information to the right customer at the right time to improve and maintain the health status of our beneficiaries across the entire continuum of healthcare. This also includes the fact that we will be looking at 75-year lifecycle minimum of an electronic health record for each of our beneficiaries.

In January 2010, our IMIT strategic plan was approved, which set ten goals to accomplish in the next five years. These goals include focusing on evolving our health information architecture, advancing our IT interoperability to create fast, easy to use, accessible and reliable health IT products and services, and in support of electronic health records in advancing a personal health agenda for each of our beneficiaries, hence our emphasis on supporting health IT standards, vocabularies, and progress towards full healthcare interoperability.

I'm going to only address certain of the questions that my testimony has answers to all ten. I'd like to highlight that under question four, how should subsets and value sets be described, what's the minimum set of metadata, we would also endorse with our mobile and diverse population that we use the ISO 11179 and metadata and the additional for vocabularies to help do this. We have treaty obligations with NATO, and we have international health agreements with other nations. And that, to us, is extremely important that we work from international metadata standards.

In what format and what mechanism should subsets and value sets be distributed? Electronic access and distribution has worked for the lone academic searching for medical concepts, but not for the runtime software developer's environment. For example, having the unified medical language system on a CD does not mean that a developer now has terminology content in digestible format, as he told me he thought that he could now run his ESB terminology services because he had a CD.

There is a huge learning curve. There is a learning curve for developers, and they say, wow, you know, and we need to. The distribution mechanisms should support the formats that enable software vendors to

easily capture what they need to serve specified use cases such as HITSP information specifications, or to serve a particular domain, a clinical domain function such as pharmacy. It has to be intelligible for them to be able to support their projects.

Regarding what is the best practices that we have learned, the MHS has had several projects over the last ten years, including trying to stand up a terminology service bureau. And, over the last five years, has been generating computable allergy and duplicate medication alerts in some information sharing with the VA. There are some good lessons learned. Concentration must be placed on essential information needs and maturing the value sets first for the provider organizations and the preponderance of care transactions, clinical care transactions.

The senior leadership in both the producers and the consumers must commit to the use of these health IT standards-based value sets. The marketplace must fulfill their requirement to respond by insuring that products and services are compliant with these and can produce their output with the standard vocabulary sets. In other words, don't make the customer try to figure it out for themselves by hiring a clearinghouse to do it for them, as we did with claims data, or we will not be able to have meaningful use at the targeted dates. It has to be able to be produced by the application in the correct format.

There is, again, there is a constant and non-negotiable requirement for consumers and producers to have configuration management and to understand the constraints and the opportunities within that. An organization's governance of terminology and value sets of provider organizations entails monthly, bimonthly, semiannual planning, and annual contracts to maintain these, to synchronize the sets, the creation and the use among its applications. We have over 25 applications in just the clinical healthcare arena alone. I'm sure many other organizations do too, and that is a critical issue on how you are going to implement those. ICD-10 planning is a great example.

Within the CM space, version control internal between applications and external between the organizations is essential. This is especially true in the areas of triggering clinical decision support in a computable fashion. DoD and VA have a bimonthly schedule of what they have to do on RxNorm versions and checking on what has to be done for allergy alerts and for medication interactions. Those are not insignificant in time, in consumption of time and efforts.

Also, lastly, value sets chosen from the same vocabulary can have very different order of precedence, concepts for different use cases, and there are some subtleties in programming for this so that an agreed upon sequence of mapping through that value set to arrive at the right concept for each particular use case can be extremely important for trading partner software. Depending on whether one is trying to trigger a duplicate medication alert or a medication allergy alert, the sequence of matching concepts to the actual patient medication order can be very different. That can cause – vendors may need some help with this and, believe me, we know. Vocabulary experts are a scarce resource, and that it's difficult to find people who can work through those issues for you on the contracts and in your own organization. People who do this have to do this frequently so they understand what to do.

On question nine, do you have any other advice? As Linda said, standards are particularly important to government agencies to insure that their systems remain open, extensible, and flexible with a minimum risk of vendor proprietary interest and lock in concerns. Not only is there OMB circulars, but within DoD, there is guidance to use industry available standards where possible. And I would just like to summarize that, for us, it is peer review and transparency, and the recognition of those is very important. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Nancy, thank you very much. I think, next up, we have Theresa Cullen from the Indian Health Service.

Theresa Cullen – Indian Health Service – CIO

Hello. I'm Terry Cullen. I'm the CIO for Indian Health Service. For those of you who are not familiar with us, we're the largest, integrated, rural, healthcare provider in the United States. We serve 1.9 million people. We're in 35 states. That is important for this discussion because our plan is to achieve meaningful use incentives for both Medicare and Medicaid in 35 states.

We're the only federal partner that's in fact eligible to go after the meaningful use incentives. As a result of that, we have been actively participating in the feedback process within Health and Human Services as a sister agency to ONC. But also, we're acutely aware of the impact of the standards, as we approach 2011, and I will share with you one example, as we go through my testimony related to one of the value sets of preferred language and the difficulties that approach that will impact deployers of electronic health records, as we move forward.

I want to start out by saying, however, we do not at the current time staff much of the vocabulary work. You guys probably have never even heard of us, or we're like a little voice on the phone that doesn't talk much. The reason for that is that we, as a per capita expenditure, have the least amount of money of any of the federal partners. As a result, we are intrinsically dependent on the work that our larger federal partners have done in this arena. We rely on them to help guide the work from a federal perspective, to give us results that we will then be able to integrate into our healthcare system.

I will tell you, however, as we look forward, we look at ICD-10, the funding for our agency does not exist to do ICD-10. Obviously we have to do ICD-10. The estimate is $12 million to $15 million. That gives you some insight into what is confronting not only the Indian Health Service, but many of the other electronic health records for people, as we try to move forward, especially for providers that serve small, rural, vulnerable populations that will have limited access to resourcing in there.

As a result of the panel questions, we've submitted responses on most of these. In order to be cognizant of the time, I'm just going to pay attention to some of the specifics like Nancy did here because I think our value to you is as an implementer to tell you what's been the issues, not what steps should be developed. However, we obviously have opinions on that also. But from an implementer, what we've really found is the frequency of subsets being promulgated and pushed out is very difficult to maintain.

We provide an integrated healthcare delivery system, however, because of broadband issues. We have a client server application, 400 servers out there in 400 sites with site managers that may or may not be technically adept at insuring that they can support the equipment that's out there and the patches that go out. So to decrease the frequency of value set, change is really critical to us.

Support services need to insure detailed implementation guidance and not just what is the value set. For instance, our implementation of LOINC, which has occurred initially due to CDC support that happened about four to five years ago, stalled because, as you know, there's been some ongoing issues with LOINC. We've turned to Clem McDonald, who is helping us now. And we've, in fact, taken the approach that one of the later speakers will talk about, which is to take what's the 95% give here and map that and put that out for us as opposed to insuring that every lab test is mapped. The reason for that is that we cannot passively map all the lab tests. At some point, we have to get into the system for that site to help them.

However, for best practices and lessons learned, our system includes updates that are relevant to our work process and delivery model. There are many areas, many domains that have not been address.

These would include predominantly what has traditionally been the non-traditional determinants of health. I would argue that there are probably traditional determinants of health and have just been unrecognized.

Areas of violence, behavioral health, areas that I think one of the CDC speakers later will address. In those arenas, because of our need to develop standard data reporting, we in fact have developed our own standards. We released them in our system. We say the only way you can collect your data is this way. For instance, when you screen for domestic violence, our guidance with that is hopefully to develop, to be able to do semantic interoperability at the time those code sets really, those value sets actually are developed. But there seems to be a distinct disadvantage for those domains, as it relates to the electronic health records.

Multiple data standards that are of dubious benefit, either at the point of care or in the population health arena, are not adopted within our system. Obviously we're going to adopt what meaningful use requires because we will have to do that to insure that we can qualify for those incentives. But it is important to note that there are some dubious standards out there in terms of what we believe benefit our patient population. We also have decided that meaningful use, in and of itself, is not a very laudable goal, meaningful use only to improve patient care and reach health equity is what's important. And, in fact, our clinicians have pushed back to a very large extent recently and said, if you can't show me how this is going to make a difference, we're not going to do it, even if there's an incentive.

The integration of new data sets is, at best, a burden for communities and healthcare systems with limited resources. Promulgation and acceptance of data sets must include an ROI scenario for the electronic health record vendor, as well as the end users. If standards are developed that cannot easily be integrated or cross-walked in a passive way, their adoption will be delayed or possibly not attempted.

The one example I would give you is that you're probably aware, meaningful use includes preferred language. Preferred language is a very difficult standard to come up with. And, in fact, when my preferred language for many of my patients is Navajo, it's even a little more difficult, or…. In our attempt to integrate a preferred language value set into our system, we looked high and low. We, in fact, in a sense, modified what's considered some standards so that we could make sure that we could get the value set in there that would, in fact, be of benefit to our providers.

In conclusion, we would recommend there's an independent, central coordinating body, that clinical content be managed by experts, and that, in fact, the vocabulary domain pay attention to data that addresses these nontraditional determinants of health. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Terry, thank you very much. I will open it up to the taskforce members for question. Yes, Stuart first.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
Theresa, I'm struck by your testimony, and particularly because one of the things that I don't get a strong appreciation for is what the implementers have to deal with. And I wondered a little bit about meaningful use and what you saw as meaningful use as opposed to what I might, and from a more academic point of view, see as meaningful use.

Theresa Cullen – Indian Health Service – CIO
I came here last night from our clinical director meeting, our national clinical director meeting, and what we have decided is that we're going to turn meaningful use on its head. We have an improving patient care initiative, and what we have elected to do is develop a glide path that insures that meaningful use to

meet the health IT incentives, which are not insignificant for our agency. There are hundreds of millions of dollars, so it's very important that we attempt to reach meaningful use.

But that we will make meaningful use a secondary goal to improving patient care. If we do that, then there are things in meaningful use that we believe may be impediments to our system, not in 2011, but as we move towards 2013 and 2015. And we've taken our opportunity as a sister agency to CMS and ONC to perhaps vividly comment on what we believe is doable and makes sense to do, especially in rural communities.

For us, interoperability is the most important question. We definitely spend over a billion dollars in the private healthcare sector. The vast majority of that goes to other small, rural providers. We need the small, rural providers to be up on an electronic health record that will enable us to share information. We believe there are many obstacles to that goal.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Who is next? Other questions, discussion?

Bob Davis – Siemens Medical
This is Bob Davis, and the point that was made about the difficulty of preferred language, I think, brings up an important point for what this whole discussion is about in terms of governance of these value sets or the "standard value sets" because I know there has been work for the state of California who needs to collect the preferred language, and that work has been done through administrative transactions, both the NUBC, UB04, and also an X12 transaction. We've worked hard and long with the joint commission to try to come up with definitions for what this is, and I think all it does is points out how important it is to provide governance over the standards that are going to be used in healthcare.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, Linda.

Linda Fischetti – VHA – Chief Health Informatics Officer
Thanks. To the speaker who just asked a question, you were talking about governance, and the question that I have relates to, are you just referring to governance of value sets, governance of vocabulary subsets and how that takes place, or are you talking about governance in the broader context of where all of us, as providers are going? We are looking at governance of NHIN, all of the standards that are related to that, and configuration management of NHIN standards versioning. We're looking at also engaging with NHIN Direct, and the governance is going to be related to that and the changes related to that.

We're now having, in some ways, an isolated conversation related to governance of value sets. Truly, I believe what we're looking at is eventually a governance structure where all of the implementers are able to submit lessons learned, share the experiences that we're currently having, as we find wobble in the standards of NHIN currently, I'm sure in the future in NHIN Direct and the value sets. And where does all of that go, and how do we all version at the exact same time?

Nancy did mention configuration management, and so thank you for the question related and the comment related to governance. I'd be interested in, when you say governance, what exactly is it that you're thinking of?

Bob Davis – Siemens Medical

I'm thinking big picture, and this is Bob Davis again, and I'm thinking big picture and small picture because I think they both work.

Linda Fischetti – VHA – Chief Health Informatics Officer
Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'll pose a question, and I think this is primarily probably for Nancy and Linda, but Terry, please chime in also. I heard in, I think, all of your testimony, a preference for the federal government to play a coordinating role as a central authority, but then to have open, consensus based, standards development processes where I think mostly Nancy and Linda resources are relied on by Terry, as I heard it, to actually go through and participate in the standards development activities.

Relating this panel back to the previous panel where we had the discussion with Doug about the actual fragmentation of standards development resources between different venues and different processes. I guess my question is, where are your resources now engaged in vocabulary and standards development, as well as binding the vocabulary value sets to the content exchange standards for meaningful use? What's your view about that question of fragmentation of resources between the existing processes and new processes such as the one Doug presented?

Linda Fischetti – VHA – Chief Health Informatics Officer
I heard two questions. I'll go, and then Nancy can go next. The first, you implied actually that government would have a role in governance, and in my testimony, I think I pretty explicitly pointed to the OMB directive, A119, that provides the principles of an organization that the federal government is allowed to participate in. And I stay pretty judiciously away from exactly what the government should do and even more judiciously away from who in the government should do what. I think that if we look at the principles and the outcome, that's where we would like to have that conversation. For example, HL7 messages are not in any way governed by the U.S. government, but it works.

Then secondly, you talked about fragmentation of resources in terms of engaging with standards organizations, specifically in support of meaningful use. It is critically important for all of us right now to support the Office of the National Coordinator at Health and Human Services in their goal of meaningful use. This is a historic time for the country. This is an opportunity to get alignment of standards in such a way that we've never seen before. This is an opportunity to set up that national governance that will not only get us through the next few years, which will seem like five minutes when we're done with them, but will actually take us well beyond that.

We, as a federal health provider, are used to create our own value sets, and that was something that we did internally. Now we see that activity is something that we will be consuming more from outside, and we need whomever is doing that to be doing it in such a way that we can participate, as well as consume efficiently, as Terry say eloquently said.

Now in terms of, are we shutting down all of our other standards activities to be able to support meaningful use? Absolutely not. As you can imagine, somebody who is administering over a million medications a day, we have a need to improve the standards by which those medications are labeled. This was detected by our bar code medication administration activities. We are working with GS1 to make sure that we have standards for labeling of small doses that are as rigorous as they have in retail, and so we have needs that, right now at this moment in time, are a little outside of what the immediate focus is within HHS, understandably. But we believe that this will be part of the national contribution that

we're able to make in our standards footprint, which is in fact broader than what the national conversation is at this moment in time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Hello, Jamie. How are we devoting our resources at this point? I think one of the points I made before is that this round of meaningful use criteria is basically consuming a lot of vocabulary standards that we spent the last seven years creating. And one of the things, as federal agencies, is to still have a commitment to be looking three years down to make sure that there's still more stuff to be consumed in a couple of years. One aspect of that is, I'm working also with GS1 in our medical logistics and FDA at medical device metadata. It would be great in three or four years if we had, in the patient care summary, a list of computable data on medical devices, so we're looking at what we need to do to get that put out and to be able, and get manufacturers to comment back.

That's actually a three-tier process because it's not only do you have to get the suppliers to supply it. We also are liaison with the medical material communities and the vendors there because we have a liaison into all the manufacturers of material management systems. What do they need to get in there, and then what, from there, needs to go into a patient's electronic health record at the point of insertion or at the point of prescription. That's one aspect.

We are trying to stay committed to look at areas that have not yet been talked about much on the national agenda, but to keep that moving forward. I will say, we are in somewhat of a – in terms of splitting information resources to organizations like X12, and we are committed to those organizations because we have a TriCare provider, you know, insurance program, and need to stay up and make sure our comments are in there.

We have been consistently working with the ICD community to make sure that military unique injury codes or injuries that are divided first in warfare are then becoming part of the injury code set for international use. We are looking at – actually, it could be an interesting time to think about the international classification of functioning because this issue of continuity of care. If we can find, we are somewhat engaged in that, but we need to have implementers get trained in this.

No one wants to force a terminology use on practitioners who don't use that in their current – who haven't been trained in it, to use it in their practice. And we would love to see an augment ed say, like who can help a training program with occupational therapists to make sure they understand what this is. That's another thing coming up in the vocabulary world, and that would be useful over time because that would enhance family engagement in their own personal health agenda if they were able to have more information in these areas of functioning and in devices and everything else that they have to do to sustain a healthy life.

We are actually looking at guidance on how this next phase goes. We've spent a couple of years involved in the HITSP work, which, as you said, is extremely time consuming and consumes very bright people's time, as well as the HL7 work. Both are important in terms of specifications. I think we, in the federal government, had not normally, or DoD had not normally gotten into the specifications work because we said the industry determines the specifications, and then we use them, as other industry members do, whether it's supply chain or anything else. We are actually probably in a pause, a strategic pause, waiting to see how, and also in terms of how we, as federal agencies and providers who actually want to help move the federal agenda on meaningful use, we also are looking at what we need to do to

supply and demonstrate that the use of our own EHR is meeting those criteria of using the right vocabularies.

Theresa Cullen – Indian Health Service – CIO
I just want to make one comment because obviously I'm so thankful that my friends here do the grunt of this work. But it is important to recall that all of us were under the – in the last administration, the President's executive order that once the Secretary endorses HITSP standards, we had to integrate them into our systems within a year. I'm reluctant to say, but the information is foible. The most we ever achieved was 25% compliance with that.

I don't think that's that far off than what the other departments were able to do, so it does give you some insight into even if standards are promulgated, endorsed under an executive order, obviously with no additional funding, to be integrated into the EHRs, how rapidly we can response. And that number, I think, was probably fairly accurate because it was subject to OMB review. But it does give you some sense of the difficulty in this arena.

Linda Fischetti – VHA – Chief Health Informatics Officer
Let me just add on that. I think the clarity on that is as a huge provider organization, we have said for years that we cannot put new data into existing legacy systems easily. It has to be with a major upgrade in software or with new development. I think that's, you can't turn a pig into a silk purse. You have to be able to do what you can do with the major software upgrades. We have never had the major issue. We've been trying to say that when we do the new development, and when we do prototypes, and we do other stuff, we will implement those vocabularies, but we can't do that if there is no place or no funding to do data upgrades.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. I have one followup for Terry, and then Marjorie, I think, is next. Terry, one of the things that, and this gets back, to some degree, resources, but also ties it back to our governance discussion here on vocabulary and the value sets that are needed. I think we're all struck by, you know, your description of the need for vocabularies around domestic violence and languages and so forth that may not otherwise be considered in some of the work that's going on here.

To the extent that we're looking at sort of who and what processes, who should do what with regard to development of these value sets and what processes, and you're representing really a rural provider community for underserved communities. What can we do in helping to set up a structure or generating, maintaining these value sets that would benefit that provider population?

Theresa Cullen – Indian Health Service – CIO
I think some of it is just a recognition of the need, and I think that has been lacking. The dialog at the national level when it comes to value sets has, I'm sure SAMSA would agree with this. They feel excluded. So even though there is – my agency is within Health and Human Services, the emphasis has been on traditional clinical care, clinical care delivery.

I think that meaningful use is going to extend that into population health, but I would think, from a governance perspective, that if the dialog got raised in terms of amplitude, and there was attention paid to that, you would find many federal and private partners that are more than willing to work with this. For instance, you may not be aware, there's a homeless data set. We've cross-walked that homeless data set into our PMS, which is our health IT system, to see what data does the homeless community believe they need to collect in order to assess the impact of their program?

It turns out there is significant overlap. Probably about 80% of their data fields are already included in our system, but the 20% that aren't included are the ones, in fact, that are unique to homeless situations. How do you define homelessness? Is it chronic? Is it episodic? It is family? Is it in a shelter or whatever? Those kinds of data, I think, in the long-run need to just be paid attention to. I believe that most of those determinants of health actually have a constituency that's already been established that have a voice, but their voice just hasn't been elevated.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. Marjorie?

Marjorie Greenberg – NCHS – Chief, C&PHDS
Thank you. Thank you to all three of you. I certainly want to endorse what Theresa was just saying and just mention that the National Committee on Vital and Health Statistics, one of this group's sister federal advisory committees, is particularly interested in this area of social and other determinants of health, and is discussing how to advance the standards and interoperability in that area, and particularly, I think, what you're trying to link, link the clinical data with population health data. As I think Christine Gebby who used to say it's not really the clinical and population or public health use different data. They just use the same data differently, and so I think that's certainly an area that I know the national committee would like to partner with this standards group on.

I think Betsy, in particular, would be disappointed if I also didn't follow up on Nancy's comment about the international classification of functioning, disability, and health. I think it relates to this issue of social determinants and other really environmental factors that are often almost the most influential aspects of a person's health status. And I think, in regard to training the different therapy groups, the occupational therapists, the speech therapists, the physical therapists, all of them, it's now the ICF is actually part of their curriculum. It's part of at least those who are coming along now in the profession, part of their whole worldview. But I definitely agree that there is no national strategy to try to get this classification and the whole area of functioning into clinical practice and into the vocabularies.

The only place that has any responsibility, I think, really in the government for this is actually my office, and we have essentially – I mean, I'm not here to be requesting funding or anything, but I mean, we have one person working on this and no funds. So I think that whether it's the VA, DoD, Indian Health Service, or the population at large, functioning is probably the most critical aspect of an aging and disabled population, obviously, and we just aren't giving any attention to this. So I would welcome this committee, as the national committee has taken quite an interest in this area, and I'd welcome if you, if this committee would as well, and be happy to work with you and anyone, any of your agencies to the extent that we can. But we really need some kind of infrastructure to advance this area.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Betsy?

Betsy Humphreys – National Library of Medicine – Deputy Director
I just wanted to comment that I really appreciated all the comments of the panel and, Terry, I appreciated your comments about the things that don't get thought about and don't get done. It's interesting, over my years in dealing with other agencies within the department and across the government, I think that we often, and attempting with some success, to be pretty good collaborating across agencies. I think that there really is this issue of resources, which definitely affects the Indian Health Service, SAMSA, and some of these other places, and everyone, which really comes into this, and we just need to address it in a much more effective way than we have done in the past.

We just have to because it's also obviously frustrating to find out at the end of a process that you forgot something like there are people in the country that speak Navajo. Yet, the people who could have said, hey, whatever, way up front in the process didn't actually have the resources or the bandwidth to be in the room to tell you that. So we've just got to do better at this. Some of the things that NCHS and AHRQ did in terms of setting up the public health standards data coordinating committee and whatever have helped in some areas, but we clearly have other places we need to go.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Nancy, I want to go back to one of the points that you made, and see if I can ask you to amplify on the need for international standards and international coordination, particularly around the standards for metadata to describe the controlled vocabularies. I think you mentioned that because of obviously the international nature of the care that's provided by the Department of Defense. But I'm hoping you can amplify on the need for that kind of international coordination a little more.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
There are a couple of key aspects to that. We have about 11 major hospitals around the world. For instance, our hospitals in Korea and Japan may very well buy medications for our base populations from the Japanese manufacturers … Germany may be buying pharmaceuticals not only from the United States, but from European manufacturers.

One of our side missions is food and health safety inspections. Many of our epidemiologists, and we have 300 of the 700 federal government epidemiologists in the DoD, have to do that in those areas where we are located and the rest of the FDA is not, for example. So that's medication issues in our materials management. I asked vendors. Can you accommodate? How is this international drug enumeration going? To the FDA because, I said, we'd have to have both sometimes.

The other issues are not only medical devices, but the issue that, by treaty, we treat, and by department of state, we work with coalition forces like NATO. Then, for instance, my colleague just came back from triaging as a family practice physician in Haiti with the 82nd Airborne. He was triaging patients coming in from the NGOs, and then determining who had to go to the USNS comfort for surgery, and who needed to go to other places. So there's a very strong working with other NGOs in these humanitarian disasters, so interoperable.

And many of us probably saw the Israelis come in with a fully electronic, modular unit in the first two days at Haiti, and you were saying, gee, we don't look quite like that, do we, when we come into place. And you're wondering what their interoperability is and their data. But again, they're from a very small country. I don't know if they were interoperable with anybody else. But it looked snazzy, I would say is where it would go.

There are some of those issues where we may wish, at some point, to transfer that initial triage examination data to some other NGO, that would be an example to give that copy. In the Persian Gulf War in '91, we came back with like 10,000 or 15,000 face sheets and put them in a warehouse, and that's where, as we started to have an electronic record, we wanted to get away from that. So those are the cases that we might have, and then for the United States, that would be another issue on being able to have some interoperability during international Olympics and maybe information sharing with Canada and the United States, etc.

Those come up in terms of, I would say a good example is under NATO. Sixty years ago, we created standard injury codes because there were no injury codes 60 years ago, and if we look at ICD now, the target would be to go towards that kind of thing. Does that help?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's great. Thank you very much, Nancy. I think one other thing I'd like to follow up, Linda, with you on is you talked about the need for developing the small, high value, value sets, I think you said, that have high face value for clinicians. To what extent are those identical to the value sets required for the meaningful use quality measures? And do you think that there is – is that part of the same process, or is there a different process for perhaps determining those priorities?

Linda Fischetti – VHA – Chief Health Informatics Officer
I'm going to defer that question to Patty. She is the one in our organization spending a great deal of her time looking at this, and she is the director of the terminology office within our standards and interoperability office.

Patricia Greim – VA – Health System Specialist: Terminology
Thank you, Linda. We are looking very closely at the meaningful use regulations and suggestions in the interim final rule related to what makes sense clinically. I don't think the results of that analysis has really been through, but I think that's an important question for all of us to be asking.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Other questions for this panel or further discussion? Okay. Then I think what we're about to do is to break for lunch five minutes early. I want to thank you all very much for coming in today and providing your testimony, your input, and participating in the discussion here. I hope we can continue this discussion further, as we go along in this taskforce. Thank you very much. We're now going to break for lunch until 12:30.

BREAK

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, we're ready to resume. If you would please open the public lines and I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much.

W
The public has joined.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Judy, thank you very much. We're ready to resume our hearing into vocabulary governance, hearing from government agencies that have experience with controlled vocabularies for relative use cases. So I think we'll just start right in with Ken Buetow from NCI.

Ken Buetow – National Cancer Institute - caBIG
Thank you very much. I'm pleased to have the opportunity to describe the National Cancer Institute's practices and experience in developing and utilizing vocabulary infrastructure. Arguably, NCI has prototyped over the last several years government coordination efforts similar to that being proposed, the recommendations of this community in the boutique community of the cancer community. More concretely, we work to create a framework where the entire cancer community can work to create and inform standards as well as building in the infrastructure to support, develop and distribute these resources.

NCI terminology is supported concentrated in the NCI Enterprise Vocabulary Services or EVS. EVS leverages and extends and informs the NLM's ULMS and provides support for the creation and distribution of vocabulary through both its terminology and metadata services. We intimately bind the two.

EVS electronically distributes in human and machine readable forms, the NCI Thesaurus and NCI Meta Thesaurus, which provides hot and cold running access to 20 separate terminologies and more than 80 integrated terminologies. Our metadata services support the creation of subsets and value sets associated with data element concepts and with a diverse collection of information models.

NCI's Open Access/Open Source, ISO Metadata Registry helps users identify or create concepts, and sets the values that they can share and can use and reuse across the broader community. NCI Vocabulary efforts are executed through an active, open engagement with NCI and other use communities in developing both content and technical aspects of the program. Community-based resources, such as Lex EVS based on Lex grid terminology servers and various end-user tools, as well as collaborative terminology development resources, such as Lex Wiki, where the community can openly interact, provide forums in community engagement and participation.

Users of the NCI services include a collection of different organizations. The Food & Drug Administration utilizes some of these services to create structured product labeling for submission of proposed labeling by manufacturers using electronic formats, devise event problem code subsets and individual case safety report subsets used for adverse event reporting. The National Council of Prescription Drug Users leverages some components of our infrastructure to support standards employed by some 200 vendors serving approximately 1,500 pharmacies nationwide.

And, of course, we have widespread use within the NCI and the CA, big systems, especially in our most current efforts to develop oncology extended electronic health record capabilities.

NCI Metadata Service, our principle vehicle for use with which within the NCI and other systems and applications there are over 135 information models represented as ISO metadata in the CADSR, the Data Standards Repository. And NCI's enhancing its terminology services to fully support the HL7 Common Terminology Services II, CTS II, with the CTS II compliant services supporting the needs for value sets, including messaging, CDA and … implementations.

NCI's environment has formal governance mechanisms that provide direction and oversight of the creation deployment and reuse of value domains, valid value lists and other components of the common data elements that compose the bulk of NCI's metadata. Value sets and subsets drawn from the terminology services are bound within the metadata domain to specific business uses are and provided with situation-specific, contextual representations.

So quickly, to give a couple concrete recommendations and advice of either best practices or challenges, some of these are "mom, apple pie and Chevrolet," but to state the obvious one needs to work closely with stakeholders to identify content, operational and technical requirements. Disengagement from stakeholders is a recipe for disaster and no practical use.

Vocabularies and value sets need robust and transparent mechanisms for input by effective communities. This means providing methods for public input for publicly defined sets. Workflow support is vital to the creation and maintenance for vocabulary subsets and value sets. And, distribution formats often need to

cover a broad spectrum of uses and implementations, ranging from very simple text files of terms and codes through complex representations of full underlying vocabulary data.

Last and probably difficult for me to overstate is the importance of support infrastructure tooling around the use of vocabularies and around the use of metadata that actually facilitate its use in electronic access; public access in the form of human and machine-readable resources as well as support infrastructure and tools to support community engagement. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. We'll go next to Nicolay Lipskiy.

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
For the case, CDC has engaged in the development of expertise information and tools that help people and communities protect their health. CDC asks that one of the leading government public health agencies that are involved in the development of content exchange in vocabulary standards on the national/international …

I would like to preface my answer to the specific questions with some general observations and comments that are based on my experience. First, I believe that the public health prevention care war groups should be added to the vocabulary task force. Furthermore, I believe that the CDC instead of local public health representatives should be included in health committees and advisory boards so that the population's health needs are better addressed from the outset. I agree with the Vocabulary Task Force regarding the needs to promote the development of effectual marketplaces of easily added and defined and obtained value sets that are described in …ways. I want to suggest that adding to the implementation that groups of well assessed terms to other vocabulary task force terminology may improve the efficiency of those marketplaces.

I believe that one of the most efficient solutions for the task of …is building of health …level value set repositories. Finally, my vision is that management of value set repositories should be closely tied to the task of development of business cases, which in the perspective of public health and population health may be …through the involvement of federal and state agencies.

There are very successful results in the development and distribution of well assessed ….CDC program project level. For example, related to immunization, public health, case certification, etc. CDC distributes well assessed primaries through vocabulary … Public health communities…together will …associated with the various HSM implementation guides, ways…7 and CDA. …contains and distributes several unique well assessed ways on HITSP and several SDO's such as …ethnicity, vaccine names and healthcare …location.

My response to the first question also requires the addition of two CDC initiatives, which were recently submitted to IHE as the extension to enhanced share well assessed profile. First, to address the needs of our partners, we shall create a new vocabulary object called Well Assess Group for categorizing the well assessed by subject or domain. For example, similar demographics of well assessed groups contain all of the well assessed in order to demographics such counties, cities, etc. The Well Assess Group will contain all the well assess laboratory tests and results.

Second, we have also created another vocabulary object, Well Assess View for categorizing the well assessed …H-7 message or CDA implementation guides. For example, tuberculosis message mapping guide vocabulary view healthcare associated inception CD implementation guide vocabulary view.

As of today we have 500 …well assess. We have 14 well assess groups. We have 59 well assess views. We have 1.8 million well assess concepts and we have 140 core systems in….

Who uses our services? The CDC programs, state and local health departments, healthcare providers, including labs, well assess developers outside of CDC, well assess implementers, researchers, AMR and public health application vendors.

We found that a …of the public health vocabulary …repository …within CDC is very beneficial for all our partners. I agree with suggestions from vendors from the previous meeting that details on what specific information need to be communicated in each element of the information model are best known by the developer of the specific requirements. With the …population health and mind, I believe that public health agencies should play a primary role in this process. I suggest for aiding the group of well assess …vocabulary task force terminology. It will help in vocabulary support of the youth cases based on the meaningful use objectives.

CDC programs and partners are urging immediate attention to develop a distribution of common clinical care and population care well assessed that are related to the preventive tasks. Examples of those well assessed are those related to …restructure such as …use, optical use, …factors during pregnancy, family health history, etc . Other requests from our partners is bringing to the Vocabulary Task Force's attention that at least secondary diagnosis within ICD-9…SNOMED in addition to primary quotes should be included in the electronic data exchange. SNOMED quotes for reporting laboratory results must be added to the stage I of meaningful use.

Engagement of the implementers in early stages of the development of the well assessed and …implementation was mutually beneficial to the …team and implementers. One of the key conditions to …success is providing support to the programs and organization that receive the quoted data via HL7 messages or CDA documents. For example, well assessed was in history…etc. Discussion of the well assessed implementation issues …is very beneficial to …development.

One of the vocabulary metadata repository functions should be provided well assessed offered in tools to create the well assessed. Also, we found that offered in tools …recommended systems as well as allow the users to create the local quote as needed.

Another recovery measure …repository function should be providing vocabulary …tools that would help implementers map the local standard vocabularies. And finally, the establishment of subscription mechanism to inform users regarding …updates and new value sets, for example, through vocabulary and messaging community or practice post on the …side is very helpful. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll go to Mike FitzMaurice.

Michael FitzMaurice – Agency for Healthcare Research & Quality
Thank you, Jamie. It's a pleasure to appear before the Vocabulary Task Force to describe the United States Health Information Knowledge Base, that's USHIK. You know, it reminds me of a time when everybody was standing around the gallows to watch Brown Paper Pete hang and a bystander said, "Well, why that name?" And he said, "Well, he always wears a brown paper hat, brown paper shirt and brown paper pants." "Really?," said the bystander. "Well, why are they hanging him?" "Rustling." So I appreciate Judy being able to put the slides up on the screen so that we don't have to rustle all these papers around.

USHIK is a metadata registry of health information, data element definitions, values and information models. It's located within AHRQ. AHRQ's mission is to improve the quality, safety, efficiency and effectiveness of healthcare for all Americans. What a great mission! Doesn't everybody have that mission?

So you know what a metadata registry is. Why would AHRQ get involved in metadata? Well, because AHRQ wants to have healthcare data more uniformed, accurate and computerized. The data is the lifeblood of AHRQ's funded researchers and of all researchers. So the more uniform, accurate and computerized the data is, the more useful and robust will be our research findings and the tools that are based upon AHRQ's research. So, it only gets to improving healthcare for all Americans.

How is USHIK, the metadata registry, how is it organized? Well, overall it contains all the data elements that are located in USHIK. It has virtual registries within it. These are portals. It has a HITSP portal, which contains HITSP's data elements and metadata, use cases, interoperability specifications linked to all of HITSP's documents. So everything is linked together as of July 15th. Of course, they just released 79 more documents, 59+ in January, so there's a lot of work ahead for us.

It also has a patient safety portal. So there's HITSP Portal Patient Safety Portal where AHRQ is putting its patient safety comment formats, questions and answers, coded and uncoded answers, into there. I expect that to be released at the end of this month and will become publicly available to guide professional patient safety organizations in exchanging patient safety event information that they receive initially from hospitals.

We have an ARRA meaningful use measure metadata portal, which has, as an example, quality measures and the data elements associated with their numerators, denominators, inclusions and exclusions. So we've kind of done double duty. We've taken HITSP quality measures, we've put them into some of the same meaningful use measurement metadata, and are presenting that to see what the look and feel of that. That's also in development. And we have a state all peer metadata portal, which captures state's all peer data dictionaries and relates them to HIPAA standards and to each other's data definitions and representations. Insurance companies like that because, otherwise, they're going to have to do 50 different formats as each state decides on its own format.

Using information models to guide people through what's in USHIK is essential. Can you imagine trying to describe to somebody what HITSP's products are if you didn't have a measure model that started with the use case, went through all the constructs, the documents, and then down to the data elements. You might never find your way through that path.

So the first question: What services are provided? USHIK's registered authorities submit their data elements and metadata to USHIK for inclusion. Now these registered authorizes are X12, NCPDP, HL7, ANSI HISB, ARHQ and others. So, they control the data that they put into USHIK. They're responsible for the data elements and their metadata. We're simply a repository for them.

We provide a service where you can do a comparison table of your selected data elements and their metadata. You can download those comparisons in Excel, XML and .pdf format publicly at USHIK.AHRQ.gov.

Who are our users? They include HITSP members and staff, predominantly because for the past four years we have devoted a lot of resources in support of HITSP, but also federal program managers and staff, health services researchers, standards developers, standards choosers and others. As I mentioned, we now have 79 documents from HITSP that we've begun loading.

I refer you to the testimony and the comments that we've received from Lynn Gilbertson, John Donnelly and Michael Lincoln for exactly how they use USHIK.

What services do we have in active development? We are working with X12 to have electronic uploads from the registered authorities. So they don't give it to us; we key it in, move it over into USHIK, moving more and more into where they do the work and they maintain the control. We're developing new portals. We have the meaningful use metadata measurement data and the state all payer patient data. Pilot projects like these exist on a parallel server for special access, and when they are completed they are put into production. That is, they are made live and you can see that at USHIK.AHRQ.gov. The patient safety portal is like that. We have like one page in it. You will see more at the end of this month.

Specification publishing, as an example, AHRQ will publish its common formats for reporting patient safety events for use by patient safety organizations in USHIK.

Measure specifications, we have a study undergoing with AFP to analyze quality measurement components and how they might be specified even more completely than they have to date.

We have nursing assessments, another study where we're studying how to store and retrieve certain kinds of knowledge. This kind of knowledge are patient fall guidelines and the data dictionaries that describe them.

Computer query, we are working on how somebody else's computer can query AHRQ's server and instruct their computer to pull out the information that they want that's in AHRQ.

CUI's, concept unique identifiers, if you were to tag AHRQ's data elements with NLM's CUI's, somebody who comes in with a use case and says, well, my use case is larger in scope than what HITSP did, they could go to the vocabularies in NLM and fill out their use case. And we're investigating links to sister agency registries such as CDC's spin pads.

What is your revision process? Well, it's pretty easy for us; not easy for the registered authorities. They update their data in USHIK as often as they desire, assuming AHRQ has the resources to accommodate it. They are the experts in their own property. They establish their own value sets, they make their own revisions. Currently, X12 is in line for USHIK updates, followed by NCPDP and then HL7. For X12, we'll be updating the 4010 and the 5010 data elements and metadata.

Advice, what advice do we have to offer? Well, based on our own experience, we would use information models based on use cases as a starting place. We'd advocate that. Then let users drill down to the data elements.

Secondly, you have to trade off value against the cost of supplying a service. For example, we have all these 79 HITSP documents. Do we want to relate every data element to every HITSP construct in there; all the capabilities and service collaborations? Or do we want to skip that and just go from the use case down to the data elements? It's a cost factor and it's a value of use factor that we have to decide.

Thirdly, advice's intellectual property has value. Preserve it. Don't scuttle the revenue that SDO receives, Standards Developing Organization receives from sales of their guidance's, their standards.

Fourth, work with users; save them time, save them money, give them accuracy.

Fifth, understand that a metadata registry has much to offer. It has governance, it has versioning, it has intellectual property protection, and can have automated knowledge loading and downloading.

Recommendations, developed well specified national use cases. And I mean well specified. Specify in great detail the standards and data elements chosen to fulfill those functions of the use cases.

Designate a metadata registry to retrieve the chosen data element information for users. Charge the SDO's to fill the gaps and eliminate overlaps.

Consider linkages among existing metadata registries and vocabulary repositories to provide greater value for the user.

And last, partner with the users. We've partnered with VA in the past two years and their help has been invaluable in helping us to meet deadlines and maintain high quality and the large scope that USHIK has. Your partners will also be people who provide you oversight. USHIK has been overseen by ANSI HISB, by the federal health architecture and by USHIK's partners. Our partners include AHRQ, CMS, VA, NCI, DoD and NHHS ASB.

Conclusion, a one-stop-shop is needed, I believe, for providing a single source of information about a use case, its data elements and metadata, and standards from which they come. Why should 10,000 people have to find the path to this information when one good expert could find the path, travel it, take a picture at the end, and make it available to all? All should save the resources and USHIK then becomes the photo album, or a similar metadata registry.

USHIK welcomes additional partners and constructive criticism. Thank you for the opportunity.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Mike, thank you very much. Next, we'll hear from Jim Case.

Jim Case - National Animal Health Network - CA
Thank you, Jamie. The National Animal Health Laboratory Network is pleased to have the opportunity to provide input to the HIT Standards Committee on its mechanisms for developing, maintaining and distributing terminology value sets. As mentioned, my name is Jim Case. I recently joined the National Library of Medicine as a health program specialist representing SNOMED CT. However, for the past nine years, I was the chief messaging architect and one of a cadre of terminologists for the National Animal Health Laboratory Network.

The NAHLN is a cooperative effort amongst the USDA Animal & Plant Health Inspection Service, the National Institute of Food & Agriculture, and the American Association of Veterinary Laboratory Diagnosticians to provide increased capacity for laboratory support of routine and emergency animal disease diagnoses, including bioterrorism using standardized, rapid diagnostic techniques.

A critical aspect of the National Animal Health Laboratory Network is the effort to standardize data, improve data quality and increase the speed of reporting laboratory results through electronic data transfer using nationally recognized health care standards. In the interest of time, I refer the committee to my written testimony for more detail, but I will only very briefly address the specific questions posed by the committee with special emphasis on the last question regarding pitfalls and best practices.

The NAHLN terminology services are housed at the Veterinary Terminology Services Laboratory at the Virginia/Maryland Regional College of Veterinary Medicine. These vocabulary subsets include tables from HL7, subsets of LOINC terms, subsets of SNOMED and a number of locally developed value sets.

In the case of SNOMED CT, and key to the progress for the National Animal Health Lab Network, the BTSL manages an IHTSDO approved veterinary extension to SNOMED CT in order to respond immediately to the vocabulary issues in the animal health community without the need to wait for semi-annual updates of the core terminology.

Current and updated value sets are delivered to users via either a manual download or they may be managed through Web services. Services-based updates are automated and can occur at any time, any day that suit the clients' schedules.

The services provided by the VTSL are used by U.S. Animal Health Diagnostic Laboratories and the USDA Veterinary Services Reference Laboratory in Ames, Iowa, as well as Veterinary Services general management areas. While the initial use of the system is intense as laboratories come online, once established the level of use tapers off unless there are changes to the terminology subset. As of February 2010, a total of 17 NAHLN laboratories used the 32 subsets that are published to support laboratory results amongst the labs.

The VTSL is currently working to overcome challenges associated with maintaining the currency with the core terminology standards to bring additional automation to the subset update process and to improve capabilities so the automated services accessed by VTSL clients. And for additional work that the VTSL is doing, I refer to the written testimony.

Maintenance and change requests are submitted by the laboratories or through an online form to the NAHLN change control board for review and approval. Following approval, these modifications are then transferred to the VTSL for implementation into the value sets.

With regard to pitfalls and best practices, we feel that this could be looked at as two sides of the same coin. By taking the converse of pitfalls, one could generate a short list of best practices. The first one that we'd like to address is building value sets without terminology experience.

There's a widespread tendency to allow that vocabulary list to grow based on user input. While user input is critical, as has been mentioned by a number of people here, in knowing what needs to be part of the vocabulary, the part that is too often left out is the oversight and guidance by individuals with terminology experience who will think through the issues that include things like: What does the user really mean when they use this term?

Avoiding ambiguity or duplication and conveying accurate meaning often require skills and terminological oversight without which the vocabulary list becomes locked in terms of utility to their local usage, which precludes the ability to interoperate with other systems. And the first step in almost every terminology standardization project is cleaning up the existing terminology before you can take it to the next more interoperate level. The bottom line here is that terminology maintenance and development should be preformed by trained professionals in a controlled environment, and that people should not try this at home.

The second is forgetting that terminology development and maintenance is an ongoing process. Vocabulary lists are never done; however, most implementers want someone to give them a list and let them get on with their development. But the fact is that the development has to center around the fact

that the list is never going to be static. New terms are needed, existing terms are clarified, terms become outdated through new research, etc., and any good vocabulary will grow, change and improve through use.

Thirdly is the cost of terminology maintenance. While the terminology standards themselves, for example, SNOMED and LOINC, may be "free" in terms of being a no-cost to users for implementing them in the U.S., the costs come in the form of technical expertise to implement and maintain subsets or versions of the terminologies for the intended users. Initial development is an obvious cost for terminology use, but, as we just mentioned about the fact that terminology is never done, the costs are going to be outgoing and this needs to be recognized at the outset.

Next is something that may be more specific in the animal health community than it is in the human health community, but that's avoiding specification of terminology within regulation. By placing specific terms to be used either into a law or regulation, it requires change in those laws or regulations in order to modify, enhance, or retire obsolete or inaccurate terms. General reference to terminology standards and intentional value sets would be preferable to the practice of instantiating those lists within regulation.

Lastly is to provide implementation support for naïve terminology users. Many who seek to utilize terminology standards focus on the words that are used in the terminology description instead of referring to the concepts that they want to represent. This often results in errors in mapping standard terminology to local value sets. Providing a ready cadre of terminology experts to review the mapping procedures in some of the results provided from these inexperienced users results in improved data quality and true semantic interoperability.

The NAHLN, fortunately, has a number of terminology experts willing to answer questions on terminology for all of our client laboratories, usually within hours of a question being posted to the NAHLN discussion forum. The NAHLN is dedicated to the creation of high quality, near real-time laboratory data for the detection and monitoring of animal health events. While we are still a small scale operation, the implementation of standard value sets and laboratory results reporting has improved the speed of delivery and quality of data used by state and federal agencies to maintain the health of our animal populations and public health, and to provide effective response to animal health emergencies.

Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jim, thank you very much. And last, but not least, we will hear from Stuart Nelson from NLM.

Stuart Nelson - National Library of Medicine - Head, Medical Subject Headings
Thank you. I'm Stuart Nelson from the National Library of Medicine. I'm in charge of the medical subject headings. I maintain the UMLS meta thesaurus. I direct the development of RxNorm and I have privilege of supervising Dr. Case. And just because I'm his supervisor doesn't mean I paid him to say those things, even though I support all of them. I have written testimony that's been submitted and I'm going to digress from that and just speak a little bit from my own personal point of view.

MeSH is now 50 years old. The first vocabulary designed really for use in computer systems, the talk about developing it started the year I was born in 1947. In 1960, the first version came out. It is a de facto standard and it's used by some three million people a day when they search PubMed, whether or not they realize they are using MeSH. I think that there's a lot to be learned from managing that terminology as it applies to managing value sets and other terminologies.

First, I have to say that being a terminologist kind of reminds me of the Chinese emperor who said that "ruling a large nation is like cooking a small fish." You have to be very careful about what you do. And I think the same is true with managing terminologies. If I can say anything at all about what I've learned about terminologies is, first of all, you really need to understand the users and the uses. You need to understand their systems.

Jim spoke very eloquently about the naïve individuals who come in as developers and who want just a simple list. You have to understand when you're changing something what needs to be changed. And understand also that when you make a change with some of these larger systems, it's like turning the Queen Mary. It doesn't happen instantly.

Having said that, I think that there are a couple things that I think are very, very important. One is the idea of versioning, otherwise known as configuration management. I think we need to pay a lot of attention to versioning and what the downhill cost of having multiple versions is. We have to maintain concurrency of use of a version, so that we're all speaking the same language at the same time.

To that affect, I would point out that having multiple update cycles throughout the year of lots of value sets all at different times of the year can be a real overhead problem for the end user. We need to recognize that we are creating an overhead problem if we're constantly changing a value set.

Then the other part of that is updates. I was just at the Clinical Research Informatics Meeting and one of the things we were talking about was clinical data warehouses and clinical records, and how to maintain their concurrency with the current vocabulary. I think that that's something that we all need to pay attention to when we're talking about creating clinical data and wanting to achieve comparability. We want to achieve comparability over time, not just instantaneously. Not just one version to another. And so we need to pay a lot of attention to that update problem. Some of us have been quite concerned about that, but sometimes it goes by the wayside when people start talking about, well, I need to do this or that.

And lastly, as I've dealt more and more these days with standards, I've become convinced that some individuals think that a standard can't be adopted unless it is perfect; that we can't adopt a terminology unless it is perfect. I can say that I know that RxNorm, by some standards, is better than four nine's perfect in terms of its coverage. But I don't think it's ever going to be 100%. So that we need to have methods of handling exceptions to control terminologies that doesn't force users into basically an inappropriate use, but collects those exceptions, handles those exceptions, and that those exceptions could be reviewed on a regular basis to see if there are patterns in them, things that need to be added in or addressed in value sets.

Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Stuart, thank you very much. What I'd like to do is I'll lead off with a question and then we'll ask for further questions from the task force members. This is really a question to the whole panel. A lot of what we're feeling our way towards is a set of recommendations around governance for value sets and convenient subsets for users and implementers of EHR technology in the context of meaningful use. Our discussions have focused on the creation of a new centralized governance entity that would perform coordination across use cases and across different creators and disseminators, if you will, of such value sets. So, I guess what I want to ask about is from your perspective if your own operations, what considerations do we need to think about? In other words, what would make it smooth, easy, effective for you to collaborate with a new governance entity that had some authority across different use cases to

make your work with that governance entity work smoothly? I want to ask you to think about it from the perspective of the end user, meaning a clinician who's implementing an EHR.

Michael FitzMaurice – Agency for Healthcare Research & Quality
I'll start off. You mentioned governance, but you also got into the users, and let's assume that there's an entity that was going to govern the value sets being used for exchanging clinical information and maybe also lead into administrative information. What would make the job easier is to know that whoever is doing it, that is supplying those value sets, is doing it with good quality in mind and a good process in mind, and is drawing on the experience of people who have done that. So I would look to what does DoD, what does VA, what does CMS have to say about this, because they all have different use cases, but they will all have to use those value sets.

I don't mind that it's not 100% complete. Having 80% would be better often than what we have today. I would look for who has the experience with terminology management. I would look to an NCI, I would look to NLM and to others, and to see is this an inherently government function or is it a private sector function. I'm not concerned with that. I'm more concerned with is it of good quality, acceptable to the users, and managed in a way that people can get access to it when they want.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Mike.

Jim Case - National Animal Health Network - CA
If I could just comment on something that maybe has been hinted around, but not really directly addressed, and that's the distinction between interoperability value sets and interface value sets, and that is that oftentimes, and especially in our experience in the NAHLN, the actual value sets that are used for exchange and interoperability are completely different than what the user sees in their information systems. The reason being is that it is more difficult to train people to infer what they mean from highly structured, semantically pure value sets than it is for them to map those one time to the terminologies that they're so used to looking at over years and years and years of history. And the creation of value sets may be useful for interoperability. I still think we have to address the usability of those value sets and what the actual display terms are to the clinicians when they see it and when they try to use it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Jim. Just to come back on that particular point, one of the recommendations that the Clinical Operations Work Group made to the National Coordinator as a response to the interim final rule was based on some of the discussions here was around the need for alternative display names for all of the adopted vocabulary standards that are clinician friendly. Just to reinforce that we're on the same page there.

Other responses?

W
And what's friendly for one clinician won't be friendly for the other one, so they have to be able to specify themselves.

Stuart Nelson - National Library of Medicine - Head, Medical Subject Headings
I think that in the governance process it's all very well talked about, concensus development and so forth. I don't know any time that you're ever going to have achieved 100% concensus on that. And I think a governance process has to include a reasonable, sensitive decision-making process.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Nicolay?

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
One more task which should be brought into the equation is the relationship between standards and …enterprise architecture. Because it should be a different link and the structure, and that's why …should be on the picture for governance of this standards and the whole scope of this project.

Also, I would like to say there are some specific areas, as I would imagine from my testimony, if you're talking about public health, population health, so they are very specific issues related to …etc., and who actually knows better than people who are involved, scientists who are involved in this response. Obviously there is linkage between developers of content, science standards which will serve for the models which will describe our information.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you.

M
Just real quickly, four key things. Transparency – who and how the governance is working, with inclusiveness, and implicit and explicit, but recognizing, I think as my fellow panelists have indicated that this probably needs to be done more by a republic model than a democratic model. That the concept that it really does make a difference having people who know what they're doing in this space, making decisions and actually coordinating the process.

Ease of access, it has to be straightforward to get to. We've heard some conversations around that. As well as ease of use. Ease of access and ease of use are not necessarily the same thing. We always try to assume that just because there's a URL for something that anybody can use it. But in fact that's simply not a true statement.

Last, which will continue to sound like a broken record for me, is electronic infrastructure to support this stuff. It has to be both human readable, but if we're really going to powerfully leverage this stuff, it needs to actually have access at an electronic level that will allow the basic infrastructures of the folks that are using electronic health records to actually interact with, consume of, pull down and read in real time some of the value sets and the other information. Because to deal with this dynamic nature of these things, people can't be going back every time and having to physically recode every time a new value set is released. There's going to have to be ways that there could be electronic transactions that facilitate the auto updating of these activities.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you all very much. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I have to preface my remarks by disclosing that Mayo Clinic and my team have a contractual relationship to maintain portions of the terminology infrastructure at the National Cancer Institute.

With that disclosure, I am struck and have been struck throughout the years by the relative overlap of many of the resources that are developed, both within the government and the private enterprise. But for this afternoon, we can focus on the government. For example, USHIK and CADSR have similarities. Thin VADS and Lex EVS have similarities. I guess the question to the panel is, how do you propose that these valuable resources, and they are all valuable, can be reconciled synergistically to achieve what Dr.

FitzMaurice I think correctly pointed out should be a single point of contact for resources that will be relevant not only to meaningful use, but to HIT standards, whether it be in public health or in clinical practice or in research moving forward?

Stuart Nelson – NLM – Head, Medical Subject Headings Section
That's a very good question, Chris, and something I often wonder about is how are we ever going to do this. Until we have an agency whose, the agency for HIT Standards, if you will, I think what's happened over time is that various a sundry developments have taken place in various agencies according to what they see as their mission. And I think one of the key questions that we have to look at is wherever things are housed, is this central to their mission or is it a step that's just necessary to get to that step. And it would be nice to have a real designated area that have that responsibility, because without that I think we're going to continue, everybody's going off in different directions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Mark?

Marc Overhage – Regenstrief – Director
Just quickly, I think one of the things that would be invaluable is to get agreement that that's important to do. I know it sounds conceptually that that should be trivial to achieve, but I think as has been suggested that in fact there's enough difference in the underlying missions of groups that in fact one of the reasons these things diverge is because the capabilities that each individual group needs in order to support their core missions actually are different enough that it's not always transparently obvious how you would actually get a synchronization or a global coordination.

My perhaps glib answer to this, and I don't mean it to be as glib as it may sound, is for us to focus on semantic interoperability between the resources that are supporting semantic interoperability. And I know that sounds more glib than I really want it to be, but in fact there's no reason that we couldn't be coordinating these efforts in a distributed federated framework to start with, the same way we're talking about trying to do the larger electronic health infrastructure. So if we all agreed to open frameworks where these can be interconnected, where we can have human and machine connected transactions, where we can actually do the automated evaluations of interconnected value sets, the harmonization of this, I think, would be infinitely easier, but we'd all have to open up those resources in order to support that.

Betsy Humphreys – National Library of Medicine – Deputy Director
I want to make a comment, because adding all of this up, ALM has collaborated with many organizations over many years and there is very often agencies have, as Stuart points out, an agency has a mission. At any given time somebody can look at the portfolio of activities within that organization and say, "You know, this one is not core to the mission and either resources are tight or alternatively we have a huge opportunity over here, we need to divert resources because of something that's very important in our mission." And so one of the things that I think we need to do, and I thin that obviously the creation of ONC gives a high level place to carry on these conversations across whatever, is if we're going to do this and we're going to say a logical place to do X is in this agency, then that agency has got to regard that as part of the core mission from now on. It can't be something which is susceptible to the next head of that agency coming in, reading his or her mission statement and saying, "You know, we've got such a big problem over here in public health, we've got to cut out everything that isn't in support of that." And I do think that just the agencies that are represented here, if we include agriculture as being represented by Jim here at the moment, look at the missions of these agencies; they are very, very different. Because NLM has, perhaps, been in a better space than others sometimes on sustained infrastructure for providing access to information of all kinds because that is actually our mission, so we get then the issue

is, well, is this kind of information part of the mission? Which is still a question; we all have the mission issue. But I do think that we have seen some wonderful collaborations that lasted for many years go away because somebody came in and looked at the mission of their agency and they were not wrong and they decided here are the highest priorities.

So I think that in moving any process forward we need to make sure that that's handled, because we don't want the whole country and the whole enterprise relying on something which is quite changeable by somebody just reading their agency's mission and making a decision.

Ken Buetow – National Cancer Institute - caBIG
Actually, both an amplification and partially response to that, because actually I'm in violent agreement with this concept that we actually have to have a stable center for this, and at the end of the day the real opportunity here for us is to actually identify what that stable center will be. The caveat, though, that I want to put on this is that we then actually have to recognize if that's going to be the case, then we have to support the diversity of the missions that are associated with what actually occurs. And while I'm going to actually sound a hair more parochial than I want to, but that being said, we understand that the Office of the National Coordinator's primary responsibilities and efforts are focused on primary care for the foreseeable future. So it's essential, than, if we're going to actually then create a sort of a national framework for this that we actually create the flexibility for those of us who are connected to primary care, but our missions are not solely primary care, have the capacity to be supported by and interconnected with these other activities. Because else we will actually dangerously create silos that may not be able to be undone for a generation.

Betsy Humphreys – National Library of Medicine – Deputy Director
I agree with you and I did not actually mean to say that I would necessarily see the concentration of all activities of this in one place. But just that if the country is relying on XY or Z to provide that piece of it, that that piece of it or the collaboration with the others to ensure that this stuff gets translated right to that piece is concerned part of the mission of that agency and we don't all of a sudden discover that there's another view of life in this agency and so, therefore, the animal health community was just disenfranchised or the cancer community or something.

Michael FitzMaurice – Agency for Healthcare Research & Quality
I want to thank Chris for the question and Betsy for drawing out of Ken a lot of good thinking on this. As far as the cooperation and collaboration, I would note that separately the metadata registry and USHIK and NCI and CDC are all based upon the 11-179 ISO IEC standard. USHIK follows Part III and Part D very well. So there's an opportunity for technical collaboration at that level.

I think what's needed from an HIT entity is, first of all, define core vocabularies form which value sets should be drawn and then obtain the property rights, the intellectual property rights to use those core vocabularies. And then in accordance with what Ken said about individual agencies having individual missions, encourage them to draw their value sets from these core vocabularies. So you have a lot of different use cases, each agency has one or more use cases, but if they draw from the same core vocabularies, maintain their value sets the same way, perhaps under the direction from this HIT institute or agency, then we're cooperating and collaborating a lot more and we're being more efficient than we are now.

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
In my mind it's not so simple to define this core of vocabularies. Why? For example, if you're talking about behavioral risk factors, we don't have vocabulary right now. So before we even start to do

something, we need to go to subject matter experts and they will find appropriate vocabulary, core vocabularies which should be added in the core.

Betsy Humphreys – National Library of Medicine – Deputy Director
I think that the issue, to my way of thinking, is not that there won't be gaps in vocabulary, but is there a logical home for the gap. For example, if we're missing a standard vocabulary for dietary supplements or whatever, where do we want that to be? If we're missing this category of tests, do we have a place that has the other kinds of tests and could we add it there, rather than starting something extra. Then you end up with a situation where somebody can develop another set of terminology within an existing infrastructure, which means, a) they're not inventing another way to build terminology maybe in the same logical structure. So, I do feel that it perhaps can't be done across the board, but I always feel that the sort of expansion of an existing vocabulary to something which is a natural extension of it or at least is logically there is a lot better than sending a group of people off into the room somewhere and they come up with a slightly different structure. Which may be "marginally" better, but it isn't because now every user has another one, they have to deal with another update schedule, another whatever. So I think that we should all be thinking about building on small number of complementary vocabularies wherever that's possible.

M
I think this relates back to one of my comments about the need to grow vocabularies in a systematic and standardized way. Part of this structure would be to create a flexible, rapid and efficient mechanism for enhancing existing terminologies to fill those gaps. We all know that the existing terminologies have gaps. And to have a rapidly responsible capability, rapidly responsive capability to provide fixes to those gaps as quickly as possible, while still conforming to the appropriate modeling and terminological operations of the standards to which those gaps are being filled.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Excellent. Great discussion. Thank you very much. Our next questions for the panel come from Marc and then Floyd and then I have a quick question.

Marc Overhage – Regenstrief – Director
Thank you for all the great words of wisdom. Dr. Lipskiy, I guess I'll target this at you just because I know a specific example that I'm curious. So if you look at the core mission of the CDC, you might think that the notifiable condition mapping table would be important to that, the data that links tests, laboratory codes to the conditions. And the agency has to do that in collaboration with a whole variety of folks, standards development organizations, the Council of State & Territorial Epidemiologist, I think, and so on. I can imagine that that presents some real challenges and that might be part of the reason that, at least my perception is, is that that particular value set has been difficult to maintain. I think the last posted update was 2005. What are some of the barriers and challenges that an agency like the CDC has? So does having this oversight body help that? I'm not sure it does.

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
Actually, you raised an excellent question…question because many organizations are involved in this business. We do have this imagined table for years and we need to…LOINC …etc., which we're doing on a daily basis. Actually, we submit to SNOMED every day new cause to update terminology, etc. And we do have this dialogue on a daily basis with CT.

The question is, we don't want to see just updated table. We want to add more logic behind the thing. For example, we want to add logic which will connect …condition with a specific criteria. If you are talking laboratory criteria and you see, for example, a …of antibodies, then I need to add category of low …which

will be responsible specifically for this disease, for this antibodies. And the next step will be to specific SNOMED part. So we definitely understand the necessity of this table, but the vision is we don't want to see just a simple table. We want to do it in a way which will support meaningful use measure for laboratory reporting, number one. And number two, you will support syndrome surveillance. Number three, it will support …public health case certifications. So we expect that within the next two to three months we will have an updated version of this table, because …right now they make some edits. So we kind of see light in the tunnel right now.

Marc Overhage – Regenstrief – Director
I was just trying to use that as an example, and I guess the key question would be what would help make that easier? I kind of hear that the big barrier has been the desire to make it better, more sophisticated, and then the fact that there are multiple organizations involved. What would help?

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
The same question that we have for any other task, we need to see business requirements. Sometimes we do not have business requirements. Sometimes we have different business requirements in a vision. An example, if you're talking about notifiable diseases, some people see that notifiable diseases are only infectious diseases by nature. But concepts are also …diseases. We have right now this meaningful use objective laboratory portion.

My very next question is, are we talking about infectious diseases? Are you talking about cancer? Are you talking about environment of health, let's say Lex screening. Should we add this one layer Lex screen and all support the communication, …etc. So this is sometimes very difficult because we don't have well developed business requirements. Especially for public health.

Marc Overhage – Regenstrief – Director
So maybe the takeaway here for us is as we think about value sets, and I think that's a good example, that we really have to think carefully about the objectives of those. I mean, if you've got a home, which we do here, figuring out the objectives in a very narrowly defined or clearly defined way will be important in order for them to be able to continue their work.

Betsy Humphreys – National Library of Medicine – Deputy Director
When you think about that, it just seems that to me listening that if, I mean, if this was defined as a goal of dealing with these five or however many there are categories of notifiable diseases, and we were going to pick these off one at a time or we were going to not let the expansion of the one that's most heavily developed have to wait while we figured out how to do all the other kinds, we might move ahead more. But the same, it does seem to me that this is an example of what happens when you say, "Well gee, this use case is just the same as this one and this one and this one. And then pretty soon the articulation of how to handle the combined use case means that the first one isn't being updated or done as rapidly because we're trying to handle it all at once.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much, Marc and Nicolay. Next, I think we have a question from Floyd.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Actually, Betsy, I appreciated your comments about ownership or the potential for a change in leadership in an organization that could change the scope. What I did want to ask, though, is Dr. Buetow, I wanted to ask in your presentation, maybe I missed it, but I didn't hear any comment about share, which I know Becky Cush from CDSK last time, or two times ago, did present some discussion about that and how NCI

was working toward it. And it seemed as if that had some, although run by NCI, seemed to have some interest in doing some kind of collaboration. Could you talk about that?

Jim Case - National Animal Health Network - CA
I'm sorry, just in the spirit of only having five minutes to talk, it's actually my written testimony where I talk about the relationship with SHARE and the other related activities like that. We actually have an ongoing and significant partnership to try to leverage and complement other work that's being done to give the specialty and special eyes to both terminologies and value sets that are necessary to support that. So it's actually a high priority activity for us.

W
There's one other point that I think is relative to the different missions of the different agencies, just to have it here on the table, not that everybody doesn't know it, and that is that various communities interact or various pieces of the healthcare community, or the same player who might wear five hats at different times, interacts with different agencies. And different agencies have different methods of probably promoting or in some cases requiring the use of standard and different ways that they can levy their requirements. In some ways if you're FDA it's regulation, if you're CDC it's via state agreements or whatever and other things that I wouldn't mention. If you're NCI, it's what you require from somebody that you pay, they have to do ABC. And then there could be, obviously there are, I'm sure, requirements on some states from the Department of Agriculture and various things. And one of the things that I think we need to factor into this process is that we could really get serious commitment across agencies to getting to this level or some level of common use of certain things. Then, we could have developed the logical plan for how to get there for each of these components. Because FDA can walk into a room and agree with us that ABC is where they want to go, but it's going to take a different process to get to the point where data will come to them from drug manufacturers or whatever, or people will be required to report adverse events in whatever way. I could, I'm sure, come up with a similar example across many other operations.

And I think that we need to be building into our planning the harmonization, the commitment of the agencies, and then some real serious strategy and tactics about what are the next five steps. And if we're lucky only one, in the case of one agency and in another case something else, so that we actually end up and build something reasonable in terms of when we think it's actually possible for all the players to end up on the same page.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. We are running a little bit over time, and I think that's okay. This has been an incredibly rich and valuable discussion.

I have a final, I hope, very narrow and quick question for Dr. Lipskiy. In your testimony, both written and what you presented, you mentioned the need for SNOMED to be included for lab results in the interim final rule. I just wanted to request for clarification, are you just talking there about the organisms or, for example, for PAP smears a very narrow set of SNOMED or are you recommending a broad inclusion of SNOMED for general purpose lab results?

Nicolay Lipskiy – Centers for Disease Control & Prevention - HHS
I'll try to make it short. Just forgive me if I will repeat something that the people already know here. So if you have a test and we need to report a test, there are two parts of test. One part is the test name. For test name we use LOINC codes. When we need to report a result, it should be another code system, which is SNOMED.

I spent several years working for Biosense, the biggest national bio surveillance program, laboratory SME. So one of the biggest challenges for bio surveillance is if you have the name of test and that you cannot do anything with the result, which is extremely big problem for public health, population care, for emergency response. So primarily I'm thinking about other …infectious diseases as a first step. And maybe several more chemistry related tests, for example as mentioned today, LEX screening. If you have a population which resides in old homes and people are tested and people need to report to local Department of Health, and there is no SNOMED code or any other results for tests, it will be a disaster. So maybe not only in infectious diseases, but also some other events of public interest at the first stage, and maybe additional codes for the second stage.

But …here supported population health, maybe clinicians you'll tell me from an obstetrics perspective, for example, some other perspective that you'll need to see more results in SNOMED codes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's very helpful. Thank you very much. So I want to thank this panel. This has been a wonderful discussion. Thank you very much for your time.

Okay, we're ready now for our next panel. I know that one of our panelists could not make it here today, Nancy Spector from the AMA. I'm not sure about others. So, without further delay, let's start with Charles Rothwell.

Charles Rothwell – CDC – Division of Vital Statistics – Director
Good afternoon. My name is Charlie Rothwell. I'm Director of Vital Statistics, which is located at the National Center for Health Statistics, which is a part of the Centers for Disease Control.

There is someone who has had my title since 1850. We've been in the business a long time. However, it wasn't until 1900 that we moved away from the Census and started collecting data from the vital registration system. And I'd like to point out that the vital registration system is a state responsibility, which we have built over top of to build the vital statistic system as we know it. But it is primarily an administrative system for registering vital events, which is a state and not a federal responsibility.

Since the 1970s, we have actually been collecting data electronically from states; which is not to say that states have been putting electronic systems at their data providers, which would be all hospitals, certifying physicians, medical examiners, coroners, funeral directors, whoever touches a vital record. Primarily those records were manual that those data providers were providing and we would determine what the data content is, what the vocabulary, if you will, was for those records through a revision process, which was sponsored by the secretary of HHS.

We've had, depending upon the certificate, we've had about 11 revisions or so over 100 years in doing this process. And then it's become more specific as data processing came about and we started dealing directly with states. But primarily, again, that was determined by how we did business with states, not how the states necessarily did business with the data providers, although certainly the terminologies had to be on the certificate for the data providers to provide. But that's the first standardization activities that we became involved in.

Now, I'd like to point out the difference is is that states have been going to electronic systems, which are in the provider's office, whether it's a funeral director's office, whether it's a hospital; whoever is providing that information. And the medical information is, though collected, separate and apart from any of the electronic systems that are in the hospital. The hospitals could use that as they so desired, but that's not, you basically have a foreign system within a hospital or a physician's office, or funeral director.

So what we're looking at now is trying to come up with standards for vital records through the HL7 standardization process, which would allow us to create an environment where we could share data between electronic systems in data providers with the vital registration. And by the way, vice versa. Because one of the strengths of vital registrations is its demographic specificity and exactness, which has not been a strength of many medical record activities.

And similarly, we need strengthening on the medical side. If you take a look at the birth certificate, it is really a medical record of both the mother and the infant. It is a perinatal record. It cries out for being able to link medical records together to then provide us with that information. This is one of the main areas that I think, from a vital statistics perspective, will be a great improvement in issues of standardization of electronic systems collecting medical information on population.

However, there are a lot of pitfalls in this. We've had several states trying to do business with various hospitals with an electronic record systems and those systems, although they have standards in the, don't seem to meet what the requirements are. There are a variety of issues that we have with our own systems that we thought that we had control over at the state end where what they say they're collecting really isn't what they are collecting. It's like having a dictionary. You have to learn what the vocabulary rate really is before you can use it appropriately. And I think we have a lot of dictionaries out there that people aren't reading correctly.

So I think there's a great danger of being able to share information that looks the same, that sounds the same, that supposedly might have the same vocabulary, but really isn't the same. And from a medical and health perspective, I think that's a huge issue. It's bad enough if you can't get your bills paid. It's another thing if you're thinking that your patient in front of you has these medical conditions when in fact the provider before was meaning something entirely different. Certainly from a public health perspective we have our concerns there as well. So, I think no matter, yes, we need to link systems, we need to have similar vocabulary, but there hasn't be a concerted quality control effort out to make sure that what it is that we are collecting is indeed the same, so that we can share between providers. Because if it doesn't happen, what will happen is what's happening right now in my area; people will continue to go their own way and a physician or other data providers will have to deal with different systems not talking to one other, collecting similar information, and that's exactly what we don't want to have. But that's right now what's happening to us.

Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. I think now we'll hear from Brady Hamilton.

Brady Hamilton – CDC – Division of Vital Statistics – Ph.D.
My name is Brady Hamilton. I'm from the National Center for Health Statistics, Division of Vital Statistics.

Just kind of echoing on what Charlie had to say, one of the demographics pieces of information that we're gathering now is multiple rates reflecting the use standards that were stipulated by the Office of Management & Budget in their revision back in 2003. And that has provided some real challenges in terms of capturing that information. In place we have the HL7 standards to collect that data. And as Charlie said, particularly in my little bailiwick of dealing with rates, the importance of making sure that we're on the same page, because the federal agencies exchanges information. The Census uses our information. We use the Census information to cap rates. So it's vitally important that we all are on the

same page in terms of these standards, the definitions and the vocabularies. I just wanted to second that point.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Thank you. Next, we'll hear from Amy Bernstein.

Marjorie Greenberg – NCHS – Chief, C&PHDS
I'm going to take a slightly different tact. What I'm going to talk about for a couple of minutes, and it's in your packets, is what we call the source of payment topology, which actually has nothing to do with vital statistics, it has to do with payment.

This started in 2000 when the Public Health Data Standards Consortium was actually part of, it was run out of NCHS. Marjorie Greenberg and others and a consortium of state and other data users actually created this consortium. Since then, it's actually become its own non-profit organization.

Starting in 2000, source of payment was identified as a problem area. The X12 has reporting guide standards, but they were not either mutually exclusive or comprehensive. So people when they tried to use them were using them more for claims and administrative purposes, they were not using them for public health purposes and didn't really care if they could compare across state or data entries or whatever they wanted to compare across. So, the Public Health Consortium identified this as a need and we came up with this topology that's included in your packets. We basically made it out of whole cloth, which I think was referred to earlier is probably not the best way to do things, but the need was there.

Since then, I have to give credit to Marjorie's group, which has been dogged and persistent – again, this started in 2000 – they've presented this topology at I think every gathering of both X12 and HL7, and eventually people looked at it and they said, "You know, we could actually use this. This could be useful. And if more people used it, or if more states used it, we would actually be able to compare data." And it's one of these just it makes sense types of things that states decided that they could use. And it is now an official external standard – I think that's the right word – and so it's run through the Public Health Data Standards Consortium.

We have annual meetings now. We did have two meetings a year, but it didn't seem like we actually needed them. But anyone can call in, have comments, any and all comments. We try to promote the topology as much as we can. And again, as it says in your testimony, Oregon, Georgia and New York State have now all adopted it for their hospital reporting.

So, California is considering it. They have a bunch of hoops I think they have to go through. Several other states are also considering it. We actually on one of our calls got some pushback from Florida, which said, "You've actually defined different types of uncompensated care. We don't know how to do that." The purpose of this topology are, one of, we think, its best features is that you can actually roll up the category. So if all you know is that it's uncompensated care, you can just put "uncompensated care" and then compare that to some other states or data collection efforts uncompensated care. If you happen to have more detail, much like the ICD systems, various systems, you can put in more detail. States have used it to code their Medicaid programs, specifically for their state at a lower level of granularity.

So we're actually, I think we feel pretty good about the fact that this actually has become a national standard and people are using it. It's not only designed for electronic data transmission. Anyone can use it. Several surveys have adopted it to code their source of …data, and we continue to work with others and try to improve it through our annual calls and other activities that we do.

So, I'd be happy to answer any questions about it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you all very much. Now we'll head into our question period. I'll start with Marjorie.

Marjorie Greenberg – NCHS – Chief, C&PHDS
I want to thank my colleagues for coming today and talking about these different data sets, our value sets. The reason I suggested that we have them is because there are a lot of, we've been talking about gaps and filling gaps, there are a lot of sort of niche activities out there or gaps that different groups have come forward – and I think Amy's description is a very excellent one – to fill. Because there was nobody else doing it or what was there was just not adequate. And I think a really interesting thing that we learned early on with the payer topology was that when we put it out there and then said we were going to open it up for maintenance, I believe it was the Department of Defense and the VA who were here this morning, who both said, "Oh, you're missing all of this information or categories that we need." But of course they hadn't been part of the process. But once it was actually recognized as an external code set by X12, and I think HL7 as well, then it was in the standards arena and they came forward and they contributed just what was needed and we were able to fit it into the topology so that they didn't have to maintain their own thing and we could meet their needs, but then also could roll up. And it was just really interesting, because it was kind of a microcosm of that.

With the race ethnicity, we also found that what they had at HL7 and X12, particularly X12, but again, was not mutually exclusive, duplicative, things without definitions, etc., and so that's why we agreed to maintain that. Again, there's a process for keeping it going.

I think as we look at this whole process, I just brought to the table some things I'm aware of. I know our colleagues from NUBC and NUCC weren't able to come, but there are activities going on in all of these environments. Terry previously from Indian Health Service mentioned the issues with preferred language. I think Bob Davis commented on that on the phone, although I wasn't able to hear completely what he said, but we just last week, Wednesday, I think, the NUBC approved this standard based on the ISO standard for language. And what we had found was like JCAHO requires that language, the patients preferred language be collected, but they had no standards for it. In fact, other groups also had these requirements. And apparently IHS had the requirement. And I believe the international standard does have all the different American Indian dialects. But in any event, if it doesn't, you can get them in there.

So there is good will out there, but often people are working not at cross purposes, but just completely unaware of others. So, certainly the need for this metadata registry or interlinking metadata registries is just evident, I think, every day. And nobody really wants to reinvent the wheel, but there is expertise out there to develop these things and we need to shine the light on them so that people can work on them together.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Stuart?

Stuart Nelson - National Library of Medicine - Head, Medical Subject Headings
I appreciate how important it is to have these typologies, and I appreciate how important it is to be able to develop your own value sets in some of these areas, but it seems to me if we're going to develop value sets, then maybe we ought to get a terminologist involved. I mean, frankly, without any great criticism, I read this and my skin starts crawling. "Non-veteran care" under Veterans Health Administration, what does that mean? Does that include everybody who's not a veteran whose only carried forward on a

Veterans Administration? Or does it mean all people who aren't veterans being cared for? And if it's that case, why is it under Veterans Care?

So, I look at these kinds of structural issues and I start saying, well, you didn't really have people who are experienced in developing terminologies there. And it would behoove you to do so when you start doing that. And maybe one of the things we need to think about is when we develop terminologies that we have people who have some experience developing a terminology involved in it so we don't run into these perpetual kinds of problems of defamation and ambiguous language and so forth.

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
That's an excellent point. The issue with the veterans in particular is those are the categories that the Veteran's Administration uses and it's there – yeah, I mean, it is. And so we can't say to them, "No, you have to use a different term." So I think there is a real tension between explaining this to the lay public and using the terminology that the creating organization wants us to use. We experience that a lot. I'm totally sympathetic to what you're saying.

Marjorie Greenberg – NCHS – Chief, C&PHDS
I do actually think that if we achieve some degree of central oversight and delegation and whatever, then perhaps we'll arrive at the point where there will be more argument behind it. Do you see what I mean? That, fine, if that's what you want to call it in your system, go ahead. But on the other hand, this is meaningless to anyone, if this shows up somewhere just in somebody's record and they're not inside the Veteran's system, they don't know what you're talking about. You know?

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
And that's true. The argument on the other side is that nobody but the Veteran's Administration would use those terms and everybody would just roll it up to Veteran's Administration care because they're the only ones who have any idea what the different categories are and they're completely meaningless to anybody else.

Stuart Nelson - National Library of Medicine - Head, Medical Subject Headings
How is this supported semantic interoperability?

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
Because it can be rolled up to a comparable category, which previously it couldn't. So it's like a Medicare Advantage plan. What's Medicare Advantage? That's a CMS term, but that's the term they use. But what most people in the public health use case would argue, I think, what we heard anyhow, is they want to know whether it's Medicare. They don't particularly care if it's Advantage or not Advantage, although some do. In which case they would know what Medicare Advantage was. So those are the arguments that occur.

Marjorie Greenberg – NCHS – Chief, C&PHDS
Yes, and they are endless and good arguments. I understand. I think that Stuart and I having many stripes of trying to deal with very large terminologies that have categories that are only understandable if you know what the other category above is. But on the other hand, this record gets sent and the other category isn't there. Do you know what I mean?

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
No, absolutely.

Marjorie Greenberg – NCHS – Chief, C&PHDS

The validity of what does this mean when I open up the thing.

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
Absolutely. Again, we welcome all, I guess the question would be if we had a, I don't know what your term is, I'm sorry, the expert in terminology or whatever that profession is, they would have to work with each of the different groups and the groups are kind of spotty. The VA is happy with it now, so they don't want to change it. So somebody would have to go back to them and say, "This doesn't really make any sense to anybody but you."

Marjorie Greenberg – NCHS – Chief, C&PHDS
Well, I think this also gets back to the point that Jim made and others made, too, which is the term that we exchanged doesn't have to be the one that you use.

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
Also true, but we would have to know what the correct term was, which we don't always.

W
I think there is a user's guide.

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
There is a user's guide.

W
Does that have definitions?
Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
Yes.

W
So, of course, if you have the term "non-veteran care," it's like meaningless unto itself. It's just anybody who is not a veteran. And I know the arguments against having any meaning in the codes, but the point is that this is a term imbedded within a broader category, as Amy said. So if you use that code, it is only associated, it's not to be used independently. It's part of a structure.

I don't want to make a great case for it, but on the other hand, sometimes, well, I won't go there, but sometimes you do have terminologists involved and it doesn't mean anything in the real world, too. So, we've got, I'm sorry, Chris. I know I shouldn't have said that. But these communities have to work together, obviously.

Amy Bernstein – CDC – Office of Analysis & Epidemiology – Sc.D. Chief
The point's well taken, though.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'd like to ask a question for Brady and Charlie that I think is relevant, it's a tangent of this question and then Floyd I think was next. I think both of you talked about the fact that meaning has to be comparable essentially across users and use cases, and that even if a consistent vocabulary term or concept is shared or is used, it may be used differently; it may have different meaning, either in different context or for different users. So, we've talked about, here in this task force, we've talked previously about the need to provide training, education, dictionary, FAQ's and materials of that kind. I'm just hoping you can provide us, what are some characteristics of those kinds of services that would make them most useful from your perspective in dealing with different users on this question?

Charles Rothwell – CDC – Division of Vital Statistics – Director
Well, we're just beginning in this, so I have to comment there. But we do feel that tutorials that are a keystroke away from the person who's dealing with a specific item or an issue is very important. So that if they want to know why it is or how I do a cause of death that there's something there for them. And

specifically, they're interested in a specific infectious disease causal chain or a chronic disease more difficult, chronic disease causal chain. How do I handle that? If there's something there that they can go to that explains it, if there's information for the medical records person that explains a certain term with a talking head that looks like they know what they're talking about and is useful would be very helpful.

We've, over the years, we've provided training to states who have gone out and provided training to their hospitals and other data providers. The word gets garbled as you go through four different levels of folks to do this type of training. And so I think with IT systems as they are now and with Internet activities, we can easily build into these systems tutorials and helps that really can make a difference without frustrating. The last thing you want to do is to every time you hit something it's going to come back to you and say, "Well, do you really mean this?"

Betsy Humphreys – National Library of Medicine – Deputy Director
Charlie, have you actually tested the use of these?

Charles Rothwell – CDC – Division of Vital Statistics – Director
New York City has.

Betsy Humphreys – National Library of Medicine – Deputy Director
Are they heavily used?

Charles Rothwell – CDC – Division of Vital Statistics – Director
Right now they are, yes.

Betsy Humphreys – National Library of Medicine – Deputy Director
That's great.

Charles Rothwell – CDC – Division of Vital Statistics – Director
But they're more in the general are and it's strictly—

Betsy Humphreys – National Library of Medicine – Deputy Director
Is it required training for them?

Charles Rothwell – CDC – Division of Vital Statistics – Director
They get CME's.

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm pushing on this only because we have years of experience with really beautifully designed short, to the point, gorgeous, this that or the other, help you do anything you want to do and people absolutely do not use these, unless they are required to use them. At least the general use pattern of online tutorials, even when brilliantly done, beautifully presented, we've just never heard of anyone who's fielded one of these where the person selects it as opposed to you go here and do this training where they actually get heavily used. Seems very counterintuitive to me, but that's what our experience has been.

Charles Rothwell – CDC – Division of Vital Statistics – Director
That could be what we will face ahead. But I will say that providing training, I'm just picking on physicians, but you could pick any group, providing training to physicians when they are in medical school and giving them a half an hour in a certain area—

Betsy Humphreys – National Library of Medicine – Deputy Director
I'm not advocating that, either.

Charles Rothwell – CDC – Division of Vital Statistics – Director

And then expecting them to remember when they finally hit an event like this at 12:00 in the evening, forget about it. And there will be many who won't take the time. But there are many who are quite interested. So I really do think that this can make a difference.

And the other thing I'd like to point out is that whenever you have vocabularies that are put together, or what I call data items that are put together that then create something else, whether it's a prematurity rate, whether it's BMI, you come up with a variety of composites, I really feel that this is something not only do you have to have similar terminology in, but we, whoever "we" is at the federal end or at some central end, needs to develop software that does that correctly. And that then is made available to vendors so that they could imbed that into their systems so that it could be used and you know that what you're getting is appropriate.

We have developed automated medical coding systems for years and folks use it because it works and it's been very successful. And they don't have to worry about what the internals are; they just need to make sure that they understand, give us the appropriate natural language and we take it from there. They don't have to know anything about ICE10. It would be nice if they did, but they don't have to.

If not, then you're not only taking the chance of folks misinterpreting or misusing certain terms, then they're putting those terms together to create a composite term and data item behind it that's completely fallacious. So I don't know if I've made myself clear there. I put it sort of in writing here, but we have that in statistics all the time where you're collecting three or four different data items and then it's up together in a specific way and then sent to some other data provider that they're going to use for something. Well, those systems that do that, there's a great problem with issues of standards of how those are created.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I think that probably leads right into Floyd's question.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Actually, so did your question was part of mine, but I'll extend on it since your last comments.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Marjorie is next after you.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
So your last comment, and you used BMI as an example, and mentioned the need to create software that gets embedded in other products is what I think I heard. So if in fact there is a clear value set to indicate a height, a clear value set or what is meant by height, a clear value set to say what is meant by weight and there is a numerical value for each, and a clear algorithm for how to calculate, then one comment would be is it the algorithm rather than software that really needs to be shared and make sure the algorithm is properly used. But that leads into my question, if we're talking about user interface terminology and the value sets to, if I were to look at a quality measure or public reporting, then there is some mapping from that user interface to the public reporting value set and in some cases it might even be using natural language processing. So what do you recommend for standardization to make sure the mapping or the NLP is properly done so you can trust the results on the other end? Do you have recommendations for that?

Charles Rothwell – CDC – Division of Vital Statistics – Director
I really don't. The medical terminology we're getting is, many times you get seemingly rare events and it's a decent medical term. Yet, in fact, it should have been plaque instead of plague, you know, something like that. And you have to accept all those terms as possibilities. But in the end, there's always going to be problems and mapping over to ours and if you're the unlucky physician that put down plague, we're going to plague you by coming back and saying, "Did you mean it?"

Maybe I'm not following what your question is, but certainly, one of our problems is that we need to have better medical spell-check's out for our community that are consistent that are easy to use, so that we get

over these problems, that take care of abbreviations, which don't mean anything to a lot of people. Or you have abbreviations that are used for a variety of terms. How do you get back to the real term?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Can I just followup quickly. As one who luckily caught a code in my own office that almost went out as pseudomonas enterocolitis when it was pseudomembranes, I do understand. But I guess where I was going with this is do you see certification of products or implementation types of services like natural language processing as a way to help with what you're looking for?

Charles Rothwell – CDC – Division of Vital Statistics – Director
Yes. And I think I pointed out in my little written part, one of our problems where we failed is that we did not take on an activity of certifying the systems that the states are implementing. And if we had done that, we'd have saved the states a lot of headaches, we'd have saved the data providers, the physicians, the funeral directors, the hospitals a lot of headaches. And by the way, I think the vendors would have loved it. But they weren't out there to build bad products, but if there would have been a certification process in place, I think all sides would have been better off.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Marjorie?

Marjorie Greenberg – NCHS – Chief, C&PHDS
Yes. Just going back to a question that Betsy asked Charlie about online tutorials or systems that are sort of just in time, that all of us intellectually think it's just what's needed. When you're certifying the cause of death, in this example, you just offer some information or query or whatever, but in practice often are not welcomed.

There is an interesting study by the French who have implemented an electronic death registration and they definitely found that they have to be very selective in the feedback that they provide to the certifiers, basically the clinicians. There was not a high tolerance for education. A paper was presented at one of the WHO meetings a few years ago, but for education just-in-time, even though it will improve the quality of data. But there's some tolerance, but not a high tolerance, so they had to be very selective and their top priority that they would actually engage with some type of educational teaching moment.

But I think there really needs to be research done in this area, because it wasn't that they wouldn't accept any education or feedback—

Betsy Humphreys – National Library of Medicine – Deputy Director
I think the issue is not so much feedback, which, granted, if you give people feedback and you give them too much, they say, "I can't handle this." If you give them some feedback and they can see that the target is important, they probably would take it and move on.

What I thought Charlie was talking about was the fact that there's a thing that's going to show me how to do this and I have to click to do it, to take a little training module right when I need it. I believe we have tons of experience, at least in other fields, to show that it's just very unlikely for people to use these things. But maybe it would be different. I don't know.

Marjorie Greenberg – NCHS – Chief, C&PHDS
If you don't want to teach them when they're not doing it, I mean, like in medical school, and people won't be taught when they are doing it, I don't know what the third alternative is.

Betsy Humphreys – National Library of Medicine – Deputy Director
Maybe an alternative would be literally to make it impossible to do the first one without taking the training. And then know that they've taken it and never bother them again or something. I mean, if you really wanted them to take training, I don't know.

Marjorie Greenberg – NCHS – Chief, C&PHDS
It's an interesting area that I think—

Charles Rothwell – CDC – Division of Vital Statistics – Director
I certainly think that we need to, we have to come to grips with this at some level, because my view of where Vital Statistics is going is that – and this may be 10, 15 years from now – is that we will still be registering events, but hopefully we'll be able to be pulling from medical records and others all the information we're now collecting through the vital registration system.

W
There's a solution.

Charles Rothwell – CDC – Division of Vital Statistics – Director
Okay? So I really want to make sure that the folks who are entering the information into medical records know what it is that they're entering in and how they should be entering it in, because I'm going to be winding up getting that stuff. So, it would be easy for folks in my area to say, "Oh, this is great. It's your problem." It's all our problem and I think the whole issue of how do you get people involved and understand what they're entering in and how it's going to be useful, how it comes back to be useful to them is important.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Floyd, another question?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
One more related comment. I realize it's not necessarily for this panel, but on that comment it may be worth it, if you don't already have that information from an American Board of Internal Medicine, American College of Physicians, that does CME credit for small pieces of information to understand what the experience is. Of course there is something that the physician gets back; they get CME's. So they're not just looking, they actually gain. But to see how valuable that is would be helpful.

Marjorie Greenberg – NCHS – Chief, C&PHDS
I do think that if people are getting something they need out of it, then we're talking in a different plateau than what I was referring to.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Other questions for this panel? Okay, I want to thank you all very much. It was a great discussion. I really appreciate you being here today and taking time with us.

We're now going to have a break for approximately 20 minutes. We will start back up at quarter before the hour.

BREAK

Judy Sparrow – Office of the National Coordinator – Executive Director
Could you please take your seats? We're ready to resume. Thank you. Operator, would you open the lines to the public, please?

Operator
The public has joined.

Judy Sparrow – Office of the National Coordinator – Executive Director
I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, great. Judy, thanks again.

So we're back from our break and with our last, certainly not least, panel for today.
I'd like to turn over right away and start with Sharon Sprenger.

Sharon Sprenger – The Joint Commission – Project Director
Thank you. I'm Sharon Sprenger from the Joint Commission and I'm the Senior Advisor for Measurement Outreach in the Division of Quality Measurement and Research. I'd also like to note that my colleague, Patty Craig, is on the phone. Patty works in our center for Data Management Analysis and is the lead for receipt and processing of both patient level and summary measure data. So when we get to the Q&A, I may ask my backup singer to help me.

The Joint Commission appreciates the opportunity to provide comments on the rules of the road for vocabulary subsets and value sets. Since the mid 1980s, the Joint Commission has been a nationally recognized leader in performance measurement and has gained extensive experience and expertise in the identification, development, specification, testing, implementation for accreditation purposes and public reporting of performance measures. In addition, our comments draw from our recent experience with HITSP's Quality Tiger teams and retooling of our VTE and stroke measures, and the CMS EG measures, the update to HITSP's Quality Standard, and in the decision-making concerning EHR data collection concepts as they relate to quality measures.

Today the Joint Commission Performance Measures, and associated co-tables, are in the public domain available to the entire healthcare community for its review and use. As a strong proponent and leader in measured standardization it only makes sense that measured developers will begin to make use of standardized value sets defined by others. We believe that to do otherwise would result in proliferation of similar, though not identical performance measures and would have a chilling effect on the comparability of performance data nationwide.

That being said, we strongly believe that each measure developer should continue to have the latitude to define the value sets from the national vocabulary list related to the measures it develops to ensure that value sets match their intended use. We learned during our recent experience retooling our measures that restrictions placed on us by external entities as to the composition of value sets are not appropriate or realistic. The determination of which value sets to use and what vocabulary codes should comprise each value set plays a major role in ensuring that future quality measures are reliable, valid and support the clinical intent and integrity of the measure. Restriction to the creation of value sets may be counterproductive to the development of clinically meaningful performance measures.

Today the Joint Commission employs staff with expertise to validate the codes utilized in our chart based measures and it's our intent to identify individuals with requisite knowledge respecting future standardized vocabularies including SNOMED, LOINC and RxNorm so that we can continue to define reliable and valid quality measures. We believe that each measure developer should be allowed to create their own business model for how they will gain access to the needed vocabulary expertise.

The Joint Commission believes that a process must be created to provide control around the creation and maintenance of the value sets. We believe this process should include the establishment of a single, centralized value set registry, which would facilitate the sharing and reuse of value sets along with providing a mechanism for public review. This registry should not only be built for the sharing of value sets between measure developers and EHR certified software, but for a future in which medical specialties define subsets and value sets, which will be adopted by measure developers for use in their

measures and by certified EHR software for clinical decision support purposes. We provided detail in our written comments concerning what we believe to be the minimum metadata that should be included with a value set, the high level process that should occur to allow owners and adopters to create and share value sets, the minimum functionality that the registry should have and our lessons learned through years of using standardized vocabulary.

In conclusion, one, we believe that the federal government should not dictate who might determine the need for value sets or who can produce and approve them. Rather, ONC should work with the healthcare community to create a transparent process that provides control around the creation and maintenance of the value set.

Two, an entity, such as the National Library of Medicine, should be designated as a reviewer of all value sets. This designation would not preclude others from reviewing and providing comments on specific value sets, but would ensure there is at least one reviewer for each set and would help ensure consistency between and reduce redundancy of value sets.

Three, the Joint Commission recommends that proprietary standardized vocabularies are not specified for use of an EHR. All vocabularies used in value sets should be in the public domain and if necessary to facilitate this, the National Library of Medicine should purchase the rights to proprietary vocabularies as they have done with SNOMED CT.

Four, implementing a single, centralized value set registry would assist in bringing the HIT requirements within grasp of the entire healthcare community not only for quality measures, but also for clinical decision support. This registry contains functionality that would help to ensure proper control of a set and decrease burden on both owners and adopters and, overtime, the process of linking quality measures to value sets will become less cumbersome as the value set registry expands with approved value sets available for adoption.

Thank you for the opportunity to provide comment as the measure developer steward and leader in healthcare quality. We value the autonomy to develop and maintain value sets to ensure the intent and integrity of our measures are met and that our measures are reliable and valid.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. And next we'll hear from Karen.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
Good afternoon. You're in the home stretch. I'm Karen Kmetik and I'm Vice President for Performance Improvement with the American Medical Association, AMA, as well as with the AMA convened Physician Consortium for Performance Improvement or PCPI as we call ourselves. And, I'll use my time today to just give you a little context about how we develop value sets, which is not too dissimilar from Sharon. And, then based on our experience, offer just four suggestions for your to consider as you further deliberate on this very important issue.

So, at the PCPI, we develop quality measures. We bring together the experts to do that. We have virtually all medical specialty societies around our table. We have 13 other healthcare organizations including nursing, podiatry, optometry, etc. And, together we look at the evidence base and develop quality measures.

Right now today, for example, if you look at the quality measures in the PQRI program, most were developed by PCPI in collaboration with others. If you look at the proposed regulation that was released

at the end of the year on meaningful use and you look at the clinical measures in there, about half of them were developed by our organization PCPI. So, we take it very seriously that our measures are used in national programs. They're also used by private payers as well as by medical boards now in their board certification processes. So, we think it's important that we make sure we develop the value sets that are needed to support those quality measures so that those quality measures can be used in a very clinically relevant, consistent way.

I would also just like to add that we've developed hundreds of value sets to date. So, we draw on those standard vocabularies be it ICD, CPT, SNOMED, LOINC, RxNorm, all that you were talking about today. We are committed to use those standard vocabularies. We draw from that in creating a value set that might be needed for any given quality measure. Simple example: who are the individuals with heart failure who should be represented in a particular quality measure.

We're also committed to make those value sets as part of the whole specifications around quality measures publically available. They're on our website now. Anyone could go and use those value sets. We also continue to be committed to then submit our work to the national quality forum for their review and consideration of endorsement.

Also, we have long felt that we need to work together and we need to make these available in a more HIT savvy way for the non-IT professional here. It became very apparent to us early on that we needed to take our specifications, our value sets and put them in to a more sophisticated language for our friends in the IT community. We were one of the first to develop a prototype on how to do that. That work, with the help of NQF leadership, is now gone forward and is actually an HL7 standard for trial use. And, we are committed to provide our specifications in that way.

So, with that as background, I just offer four suggestions from our experience. One is that it's not possible in our minds to separate the value set from the use of that value set, and I think that's been a theme from several of the speakers here today. We think that when it comes to a value set use for quality measures, and I would add also clinical decision support or the identification of an episode of care to be used for looking at utilization and cost, that we as measure developers are in the best position to develop those value sets and to maintain them over time to make sure, again, that these quality measures used in national programs are consistent and kept up to date.

The second point that I would make is that whomever is developing the value set, particularly in our world of quality measurement, needs to have that expertise in quality measurement, but also in clinical coding and medical informatics. Again, emphasized here by other speakers, but that is absolutely critical. We do benefit from having both expertise at the PCPI. In fact, we're now offering some of that expertise to others who do not have it in their house.

My third comment would be that we think value sets need to be reviewed fairly often. There are schedules by which those co-developers, be it LOINC or CPT or ICD-9 issue their updates. And so we always track them and we want to make sure that we are looking at our value sets and all of our measure specifications against those releases so that we have the current coding in our value sets and specifications.

We also believe that the value sets should reside in a registry with a Web service inquiry tools. And, someone should organize that in close collaboration with value set developers.

And, my last comment would be that we feel the federal government should not develop all value sets. They are too far removed from their use in some cases, obviously not always. We heard here today from

CDC and others. But, rather the federal government could provide funding for an entity in concert with a consortium of value set developers to develop and operate the registry and the rules for populating the registry and for versioning.

Again, all comments that you've heard from other speakers. Thanks for the opportunity.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. Judy, do we have Greg on the phone? Do you know?

Judy Sparrow – Office of the National Coordinator – Executive Director
I don't know.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay.

Judy Sparrow – Office of the National Coordinator – Executive Director
Do you have Greg Pawlson?

M
No.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So, next we'll turn to Janet Corrigan then. Thank you.

Janet Corrigan – National Quality Forum – President & CEO
Thank you, Jamie. Good afternoon and thanks very much for the opportunity to share some thoughts with the task force. I'm Janet Corrigan and by way of disclosure, I am a member of the standards committee and I chair the clinical quality workgroup. But, today, I am here representing my employer, the National Quality Forum, and not wearing my hat as a member of the standards committee, but rather the presidency over the National Quality Forum.

By way of background, NQF is a public-private partnership with over 400 member organizations representing virtually all stakeholder groups. Our mission is to set national priorities and to endorse performance measures that can be used to gauge progress on meeting those national priorities. We're a recognized standard setting organization under the National Technology Transfer and Advancement Act and to date we have endorsed over 500 performance measures. And, those measures are the first choice by CMS, private-purchasers, and virtually all that are involved in public reporting and pay for performance. It's critical that you use standardized measures to be able to make apples to apples comparisons and interpret the information.

We do a lot of our work under contract with HHS and under a specific congressional mandate that was passed about a little over a year ago, it directed HHS to contract with a private sector standard setting organization, such as NQF, to set priorities, endorse measures and to build a bridge between the quality community and the HIT community. Specifically to promote the development and use of EHR that contain the necessary functionality for automated collection, aggregation and transmission of performance information.

Under Floyd Eisenberg's leadership, NQF has been working in several areas that are critical to that quality community HIT bridge. One of them is the development of a quality data set. We essentially took the over 500 measures we've endorsed and traced them down to the data elements that need to be

captured in electronic health records or personal health records. And, in addition to that, looked at the most reliable source of that particular type of data and where in the workflow process is should be captured and reside within the EHR.

In addition to that, we are also overseeing the retooling of 110 measures, all of which are included in the NPRM and may end up being a part of meaningful use. And, by retooling, it essentially is working with the major measure developers. PCPI is one. NCQA is another we're working with. They do the retooling, but we have agreed upon common approaches for that. And, they're also using a specific tool, a measure authoring tool, so that that will then be captured in a way that it can readily be transferred over to the HIT community for incorporation into EHR's and elsewhere.

In thinking about value sets and how this whole area needs to evolve, we think that it's going to be absolutely critical for there to be a designated federal agency to provide leadership in this area. This is an area where both the public and the private sectors have important roles to play and they need to work together.

We think the first step though is to have a designated federal agency, a lead agency, that would set the agenda overall, establish a government structure, lay out some of the rules of the road and figure out how we're going to have established a registry of sorts for these value sets to reside in, and to take some degree of responsibility for ongoing maintenance. But, the government should not act alone. The users of the value sets need to have a very significant input into developing the agenda and in many cases will likely be those who develop the value sets themselves.

A very important point here is that we think the value sets will be most useful and will be most widely used if they are created in response to real life use cases. They need to be, in many ways, a byproduct of the performance measurement to development in the clinical decision support development.

Now, it's possible to define some major domains of users. Quality measurement and clinical decision support we view as one domain. They go hand-in-hand and our vision of the future is that as new quality measures role out, the clinical decision support will reside in the records at the same time so providers not only get immediate feedback on performance, they get the tools to do better. Clearly, there's others; public health, post-marketing drug surveillance, comparative effectiveness and others.

For each domain, there needs to be a coordinating structure. Now, in the quality area, the leading measure developers, the major measure developers, in NQF work very, very closely on what we've come to learn is a supply chain of activities and every part of that chain has to work well to get the intended effect. You essentially move from identifying national priorities for what needs to be measured and improved. There has to be an evidence base and practice guidelines oftentimes coming out of specialty societies. They get translated into measures and clinical decision support.

In order to be able to operationalize that, we need the quality data set and the value sets on top of that that are then used by the measure developers in developing the e-specifications. Those value sets are a part of that supply chain that all of our work contributes to. So, we definitely, as we move forward in this area, there's going to need to be a lot of communication and coordination with those specific domain areas. And, with standard setting organizations that are setting standards on the quality side and for the performance measures, our work is really interlocked and interconnected in a very significant way.

So, let me conclude by making four points. We think it will be important to have a lead government agency. It doesn't mean they're going to do everything, but somebody needs to be on first in this area. There are lots of government programs and agencies that have an interest and need to be involved, but

we do need a lead agency to oversee the entire area. That agency does need to play a key role in setting the rules of the road and in figuring out where these value sets are going to reside and in to thinking about the a good deal of the maintenance aspect of this. We also, though, need to have roles played by each of the major domain areas. And, with each major domain, there does need to be some coordinating structure to help define what value sets are needed based on real life use cases.

In the area of quality measurement and clinical decision support and those two being really joined at the hip need to be looked at together; the measure developers may well play an important role in developing value sets. Some have the requisite technical and other expertise to do that. Many do not. So, I think there needs to be the opportunity for other groups to play a critical role in developing value sets, which are a part of the standardized performance measures.

Third, the value sets, I want to emphasize how important a part they are a standardized performance measures. They're critical to our efforts to harmonize measures. We've now spent ten years at NQF working with the measure stewards to try to promote harmonization. We have measures at the community level. We have them at the system level, the hospital level, the individual clinician level and they cross settings and overtime, we need common ways of defining those measures.

The last thing you want to do is to have a measure that is calculated slightly different depending upon the unit of analysis at the level that they're applied, or you want to set a diabetes measure that has slightly different conventions for Hemoglobin A1C then it does for defining the denominator for whether you had an annual foot or an eye exam. The value sets can really help advance the harmonization agenda. They're also a part of our efforts to raise the performance bar.

So, for example, five years ago if you had a particular value set to define whether or not the clinician – a smoking measure, it probably would have been whether or not the clinician asked the patients whether they smoked or didn't. Three years ago, you would have found that it included whether or not the clinician provided advice for smoking. Three years from now in the future or five years you'll find that the bar is even higher and the way you want to define that numerator, the value set for the numerator, will include not only whether they counseled the patient, whether it was 15 minutes of counseling, whether they made a referral to the appropriate ongoing support services, whether they provide an opportunity to give a prescription for Nicotine cessation and whether they followed up a month later to see whether the patient had tried and succeeded for any length of time. So, the value sets are formed in a way that they can help us raise the bar.

And, then the fourth point is that this structure really needs to be incredibly flexible. Looking just at the domain area of performance measurement and clinical decision support, we can see new waves of different types of measures coming online over the next two, three, four, five years. We're now beginning to see the overuse measures and value and efficiency measures, care coordination measures. Much more sophisticated outcome measures and last but not least a variety of composite measures that increase the complexity of our work. They all have very important implications for value sets that we need and how value sets stay current to be able to support the kind of work that needs to be done. And, I daresay, clinical decision support is at an even earlier stage of development than quality measurement, so they'll be going up in even more rapid curve. So, it needs to be flexible. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great. Thank you all very much. I'll lead off with a question and then we'll take questions from the task force members. I want to start off with essentially the same question that I asked our federal provider panel earlier in the day, but sort of the flip side of it and that is the calls for the need to prioritize value sets that are highly valued by clinicians in the exam room for direct care. And, obviously here we're talking

about value sets for secondary uses for quality measures. I want to ask you how you see or if you see differences in those priorities and how to coordinate across the different priorities given that there may be some limitations in terms of the ability of EHR implementers to absorb and really make use of different groups of value sets at a particular time.

Janet Corrigan – National Quality Forum – President & CEO
Jamie, that's a great point. I want to challenge though the assertion that quality measurement and clinical decision support are even secondary uses. I think in many ways, with the HIT platform coming into place, we have an extraordinary opportunity. I will grant you in the past quality measurement and public reporting clearly was a secondary use and we're very much aware that in some cases leading institutions with HIT platforms had a separate set of measures for their quality measurement and internal improvement from the ones they were using for public reporting.

I think, though, with the NHIN, we now have an opportunity to bring those to and think with each other. Quality measurement should be a byproduct of the care process. It should provide immediate feedback to clinicians as should clinical decision support. I would agree with the comment made earlier by some of our colleagues in the federal programs is that I do think we need to be very parsimonious in the value sets that we create, and to think twice about we need a process so that users have the flexibility to develop value sets and propose them, but if it's just slightly different from one we've already got, we may want to drive towards using the one that we've already got because the last thing we need is a rapid proliferation of hundreds or thousands of value sets. It will not help with harmonization. It will not bring down the cost of measure development or EHR development, and it will confuse providers on the frontline.

We also had scarce resources to develop and maintain these, and maintenance can be an expensive effort here. So, I do think a coordinated collaborative process driving towards parsimony that identifies the most important ones would be best.

Janet Corrigan – National Quality Forum – President & CEO
I would just add that I think the process that we use to tap our extensive clinical network, multi-specialties, multi-healthcare providers, we're asking them the fundamental question whether it's a value set for the practice of medicine, which is related to clinical decision support and measures. It's the same fundamental question when we get them all in the room. You're caring for a patient with heart failure. You are providing preventive care to your population. You are caring for a patient with diabetes. What do you need to know at your fingertips? What is the terminology you use? How do that need to be entered so it is most easily accessible to you? That's the core of the question and from there then we put together what would represent a quality measure there, what would represent clinical decision support, etc. So, I think we have the pieces there to do all.

Sharon Sprenger – The Joint Commission – Project Director
And, I would just add to, I mean at the Joint Commission, we've always had the philosophy that we have never ever said what data do I have therefore what could I measure. We have always said what is it that is important to measure and therefore what data do I need. I also think though if we look at many of the activities that are occurring at a national level and in particular at the National Quality Forum and the work they're doing with the National Priority Partnership and even some current work they're doing with measure priorities. I think that you start to see really the framework in terms of where priorities are.

I also think, as Dr. Corrigan mentioned, if you've looked at the EHR and how it can look so different in the future in terms of measures that you would find, for example, that Karen and I talked an awful lot and that whether we're looking at a hospital measure or physician measure, we have many of the same priorities

and the EHR will probably help those even come closer in harmonization. And, in addition, the Joint Commission, for a number of years now, has actually aligned with the center for Medicare and Medicaid services and we actually have measure sets that are exactly aligned with them.

So, I think what will happen in the future is that there will thus be more harmonization and actually probably there won't be as many priorities through value sets because we'll be able to share those value sets.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great, thank you. I think Floyd is first.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
All right. First as a disclaimer, first of all, I work for Janet. Second of all, I was a co-chair of the … tiger team and I am directly involved in retooling measures with AMA and NCQA at the moment. So, my question is about value sets created, Karen at AMA or PCPI and Sharon at Joint Commission, when each of you might be looking at the same condition and each of you is maintaining your own value sets. How would you envision a world where Sharon, perhaps, needs a value set and thinks there needs to be modification in one created for PCPI for the same condition and vice versa?

Karen Kmetik – AMA – Director Clinical Performance Evaluation
That's an important point, Floyd, and I think that can be accommodated. So, if we first develop a value set for patients with diabetes or heart failure and we are using it in a particular use, a real life use, for someone measuring the quality of care in an … setting say, we would develop that value set. We'd be happy to share it with a register wherever entity is formed. We'd like to be the designated maintainer of that. We would date it. We would say our use. We would say the version and we would keep it up to date.

I would imagine if Sharon then looked at that and said, "Well you know what, I'm looking at a slightly different population for a different use, perhaps in the hospital. I need to add a different code set." She would be able to do that. Again, documenting that, making it available for everyone, the use, the version, etc. because someone else may want to use the same version that she's created.

Sharon Sprenger – The Joint Commission – Project Director
And we obviously spend way too much time together because I would have to agree with Karen. And, I think the other thing too is if you look in our written comments that we provided, if we had a centralized registry and we knew who the owner was, we would know who to work with. And, at the same time, as vocabularies are updated such as SNOMED or LOINC, as the owner and others that are using those value sets, we would be notified that something has changed so that we're aware too if we need to make a change to that set.

And, then one of the other comments that we offered too was that it may be that over time I need a different value set but there's someone else who's using the value set that I initially owned. So, we also think there's an opportunity perhaps then they would want to adopt that measure set because I need to go to a different value set to meet the incentive of my measure.

So, I think there are ways if we have these structured process that in fact it can work. And, I think in the future, it would just, again, really add to measure harmonization and hopefully over time there would be the need for less value sets because we could share among each other.

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Do any of you currently work with measure developers in other countries?

Karen Kmetik – AMA – Director Clinical Performance Evaluation
We are actually doing some work internationally, but in this case, we are actually the measure developer. But, for example, we're actually doing a project right now in Portugal with Siemens. But, we are actually the measure developer, but doing work with Portugal.

Janet Corrigan – National Quality Forum – President & CEO
One of the things that I think is going to be potentially useful is the international health terminology standards development organization that owns SNOMED now has acquired a toolset that is going to be jointly used by a number of different countries that are members of the organization. And, one of the features of this is that you will be able to see value sets that have been developed like in Canada or by the National Health Services something. They're moving forward to the more distributed model of this. There's some expansions that need to be done, so it will be a little while.

But, I am thinking of the fact that we need to figure out a way to make this view of value sets that have been developed in other countries available to measure developers here in the United States because if you are coming into a field where maybe the National Health Service in the U.K. or in Australia or whatever has done something may not be, I wouldn't necessarily imagine it to be perfectly appropriate, but it might be better than starting with a blank sheet of paper.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
… our interactions have mostly been with the U.K., our colleagues there, and it's mostly focused on testing of measures and integration of the measures into EHR. So, we've had periodic exchanges with them, but I'll put this item as an agenda on our next call. It's a terrific idea.

Sharon Sprenger – The Joint Commission – Project Director
And this is Sharon. I just want to comment too that's an excellent idea and we actually have done other work because we do do accreditation internationally and are very interested as are other countries in terms of using measurement and accreditation. So, that's an excellent suggestion.

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Yes ….

Janet Corrigan – National Quality Forum – President & CEO
Well, at NQF, we have some other countries that follow our work and tap into the standardized measures and attempt to use them. One of the major impediments is that we really have a different platform, data platform, than they have in other countries usually. As we all move into the HIT world, hopefully some of that we can overcome.

There are efforts that we're involved in that has to do with trying to promote global standardization of terminology that relates to reporting serious reportable events and near misses under the whole safety area. That's where I think some of the standardization has reached the U.S. and other countries. But, it would be terrific because it would also lead to the specification of measures in consistent ways and the potential to make comparisons across countries.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
Yes, and I feel we're just getting up to speed with this new platform and we'll have to move forward, but my expectation would be that at the very least the interesting value sets put together from SNOMED by

another country could at least be imported into an environment where it could be like a rough draft or at least a reference source for people who are working on them here.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great, thank you. I think Chris Chute is next with a question.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you. I have two questions actually. One is terribly abstract and the other is quite concrete. For the abstract question, I was struck by the articulation of many of you that you believe, and I don't disagree, that the quality measure developer should have the opportunity to develop the value sets that they need for particular use case and shouldn't be constrained or otherwise restricted from developing value sets. That's contrasted with Janet's statement that's saying parsimony's good. We don't want proliferation of value sets. And you've both addressed the question of sharing and overlap and so on. To what extent is there enthusiasm for module value sets?

I mean we could quibble that the parsimony issue is moot if we're all using the same terminology sources. You could get interoperability conceivably at the concept level, but that's really abstract. But, back to the modular thing, if you are both in the same domain, say inpatient versus outpatient, and the value sets you really want are mostly overlapping but you've got some exceptions in the corners, the way HL7 had defined value sets, this is all Stan's fault of course, was the notion that they could be interleaved and nested in a sense. So, you could have a value set that was comprised of other value sets.

So, when I'm talking modularity, I'm really saying let's say you're working on similar issues. You both agree on a core, but then you have an implementation, which is by its value set A plus these other two components whereas in another sense it would be value set A plus another half dozen components where there's agreement on these modules. Is that practical in your sense?

Janet Corrigan – National Quality Forum – President & CEO
I'm not sure, but I guess I think of one issue and it's that we're kind of moving in the measurement and the reporting world and in our payment world, we're moving towards this concept of a patient focused episode. And, we're interested, for example, how well a diabetic does regardless of whether that diabetic happens to be hospitalized for a period of time, whether they're in a nursing home, whether they're in the community with or without home health. We really don't care. We care about how well they perform, whether they got the necessary services, achieved the desired outcomes and whether it was done at the least appropriate cost and most affordable way.

So, I think we have to be careful about some of these concepts. At the end of the day, it's really important when we use measures for public reporting and accountability purposes and increasingly it's being driven by all the new payment programs that are coming along here. We really do want a lot of consistency, standardization, harmonization of those concepts so that we know that we can make comparisons of the outcomes of the diabetic in one setting versus another.

The other comment I would just say too is that I think we have to be careful. Some measure developers have the capability to develop value sets. A lot of measure developers don't have the capability of value sets. There are quite a few measure developers. We probably have measures in the NQF portfolio from well over 50 different developers. Now, here at this table, you have leading measure developers that account for the bulk of those measures, but there still are many others out there. The capabilities of a colleagues organizations are very advanced. They do a lot of work in this area and have a tremendous amount of history.

So, I think we do have to have a flexible way to allow those that are closest to the uses, that know the most about what would be most useful in that value set, to do it when they're capable. But, we also need to be able to have others that it can be farmed out to when they're not.

Sharon Sprenger – The Joint Commission – Project Director
This is Sharon Sprenger. And I think, like with anything, you have to be cautious as you're going into this. Historically, as we've built measures, we've always, if we could, have used data elements across different measure sets. So, if you were to look at our technical specifications, the first thing we'll always do when we're building measures is say, "Gee, do I have something I can use that would work?" And, in some cases, I can add another reliable value to make it work.

But, with respect to doing modules, I guess just be a little cautious and I'll give you a real example that we faced when we were doing our work with HITSP with our VTE set because there was a rule with HITSP that we could not do post coordination. So, we … VTE measure and there isn't a SNOMED code for DVT. And so, on the surface, that would look fine. However, our measures address acute onset. So, our value set would not only need the SNOMED code for DVT, we would need the SNOMED code for the clinical course and we would also need the SNOMED code for acute onset. So, on the surface, it may look like it would work, but I would really have to dig down deeper to make sure that my measure intent and integrity are maintained.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Now for the concrete part, many of you have articulated the notion that the source vocabulary should not have intellectual property incumbrances. Whether they're open public domain or not we could quibble, but they shouldn't be encumbered. What is your notion about the resulting value sets? Do you see any role for intellectual property restrictions on value sets per se?

Janet Corrigan – National Quality Forum – President & CEO
Chris, we in the measurement area deal with this a lot. In terms of performance measures, it's been a real and critical issue as sort of intellectual property. We don't view having intellectual property as a negative. In fact, it can really be a positive because if somebody has the intellectual property over something, they also have ownership. They maintain it. They have an investment in it. You know who to go to to take care of it and look after it.

I think the issue that's most concerning to us is that we do think that value sets and we really prefer performance measures overall, but value sets need to be available to everyone free of charge and you should be able to have immediate access to them. Whether or not there is a steward or owner that has a degree of intellectual property is sort of a secondary issue.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
I would just echo that. We think it's complementary not burdensome. So, there's value, we think, in us saying we will maintain the ownership of this value set and we will keep it up to date and we will inform you where it's being used and we'll listen to anyone who thinks something should be changed there that that's valuable. But, we make all of our specifications publically available.

Janet Corrigan – National Quality Forum – President & CEO
I will say that one of the things I think that wherever this registry ends up residing, one of the critically important things will be when you do have different owners of value sets in this case and if you are going to rely on them to do the maintenance, you really have to think through the maintenance process. And, I think there's going to be sort of two types of maintenance here, probably even more than that. There's going to be all the maintenance that's the result of changes in SNOMED terminology or all the underlying

vocabularies and terminologies that's used. But, then there's also going to be value set maintenance that's the content. It's because the users have changed and they want to remodify those value sets, like the example I gave earlier around the numerator for smoking measures.

Both of those are processes that really do require resources and you have to really monitor it very, very carefully and have mechanisms to make sure that they take place. And, if you have lots and lots of different owners of value sets, that can be complicated. It may be workable, but you've sure got to have somebody, whoever that lead entity is, that's making sure that's happening on a regular basis.

The process of maintaining and updating also needs to be coordinated with other critical processes in that supply chain that I talked about. So, we have processes for updating and maintaining performance measures and the last thing we want is a totally different schedule for the value sets that are being used in the performance measures. It has to be done in sync with the other updating processes or we're going to find that the performance information coming out it's going to constantly be changing and you can't look at change in performance over time or across institutions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, Stuart.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
Well, to follow along with that, I was a little puzzled with kind of the in my mind difficulties suggested in that the NLM should support the creation in the intellectual property so that all of these value sets could be free. But, at the same time, nobody should say who shall review and approve value sets. We should just take them all, and is kind of I guess I've been through the budget wars too much. I'm sitting there looking at it. That's kind of an open-ended commitment that we're being asked. Sharon, maybe you want to clarify a little bit about the difficulties in that.

Sharon Sprenger – The Joint Commission – Project Director
I guess I would ask my colleague, Patty Craig, if she wants to comment. We just think that it's important that the vocabularies etc. that we're using are in the public domain. And, we did outline in our written comments that if we were to be owner of value sets that there would have to be a process in place in terms of if we were coming up with a value set no different than we currently do in many of our processes at the Joint Commission for measures where we have a period of public comment.

So, there would need to be, for example, a period of public comment with respect to the value sets. And, then we actually said that the owner would have to say why or why not did they not except something that was said with the value set. So, there would have to be a very structured process in place with respect to the creation of these value sets. On the other hand, if a value set existed that we could adopt, we would do that.

And, Patty, I guess I would ask if you have other comments.

Patty Craig – The Joint Commission – Associate Project Director
No, I actually think you stated that very well. I really do think moving forward that the measure developers will be able to work together and create the value sets and adopt the value sets in such a way that we'll have fewer of them in the future. But, we really do need the ability to say if you're looking in a diabetes measure and that measure perhaps is looking at all of the different lab values, but yet we have another diabetes measure that's only looking at patients with a specific set of lab values. We need to be able to create that smaller subset value set from the bigger one and not be told, "No, that measure has to use the other value set," just because it was put into existence first.

Sharon Sprenger – The Joint Commission – Project Director
I think there will need to be some review and approval processes in place and I think that in part you saw the compelling reasons that there be something of that nature within specific domains because there needs to be an honest broker that's going to help to look at if the Joint Commission wants to come forward with a new value set that's kind of like one that's already in the registry and being used in other quality measures. It's going to be important to sort through that and decide do we need to.

In some cases maybe we do and you have to be very responsive to it. But, to me that's part in parcel of harmonization and performance measures that get put in place. They're then, however, I recognize that these value sets are used by other secondary users and that's where I think there does need to be rules of the road set and probably an additional process that helps to harmonize across the major domains of use.

Stuart Nelson – NLM – Head, Medical Subject Headings Section
My concern with that was just in terms of supporting the development of these value sets, these measure sets, it's kind of an open-ended commitment there if you ask somebody like the library to finance it.

W
… didn't hear that in these comments. But, maybe it was there but I didn't hear it.

Sharon Sprenger – The Joint Commission – Project Director
Financing is a real important issue because if you have a lot of different groups that are developing value sets there is the ongoing maintenance of them. And, some, we find this with performance measures, where we endorse performance measures and we rely on the stewards to maintain the performance measures. And, we do go through a process of an annual review, a quick review and very comprehensive review, every three years and maintenance is a critical part of that.

I would tell you that it's really variable across stewards of measures and I have no reason to believe it would be any different if you had hundreds or thousands of people who owned value sets. So you do have to really think about it, whether there's adequate resources out there to rely on those who develop, in some cases there are, but to also have a mechanism to make sure that it's happening. In some cases it will be and some it won't.

Janet Corrigan – National Quality Forum – President & CEO
One of the advantages, and I guess Stuart's comments in writing sort of address this that one of the advantages of having some level of central coordination here is that there's one thing about governance of the measure that is what gets to be in it or even the original selection of the vocabulary. And, then there's another level of QA, which we are familiar with because we ingest somewhere around 150 different vocabularies into the meta thesaurus. And all the people who develop these vocabularies are intelligent, well-meaning people and everyone can make a mistake. I mean, we've been known to make a few ourselves.

So, the issue is actually before something becomes an official, the next measure set, that in addition to the fact that the content experts and everybody has done it that it either has been developed in a tool environment where you absolutely cannot put in the wrong code or put in some strange little thing that isn't the current valid version. Or, alternatively, you go to deposit it and there actually is, which could also work, there's sort of you go to upload your measure and you get back the QA that says we can't find this thing in the current version of LOINC or whatever. And, I think that as we go to this kind of central business and everybody's trying to do this in a very automated way, we're going to have to be sure that

we figure out how to do this and then we get it built in wherever, perhaps at multiple places, depending on the sophistication of the different measure developers and what kinds of tools they're using.

Betsy Humphreys – National Library of Medicine – Deputy Director
I would just add to Sharon's earlier point that it's not in our best interest to keep propagating value sets. It's a lot of intensive work and also we would then receive criticism from the clinical community saying, "Why in the world do you have two of these and why are they different?"

So, we do spend time upfront seeing does anyone else has defined this that we can borrow, use. The incentive is to be parsimonious, making it different when we need to for clinical relevance.

Sharon Sprenger – The Joint Commission – Project Director
Yes, this is Sharon. And, I just want to recognize, I certainly appreciate there's a cost, but really what we were doing was recognizing, I think, the expertise that is at the National Library of Medicine and that someone really needs to review all the sets to make sure there isn't redundancy and that we are consistent and that over time there would be less sets. So, someone is going to have to be that entity that can really be the reviewer of all value sets.

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes, one of the things that we also see as a real research and development opportunity is this notion of, and this is an area where we're certainly interested in this and there are, I'm sure, many people elsewhere and in this room who are interested, is this notion of how do you detect a change in a vocabulary that really needs to be brought to the attention of the measure developer. And, can we develop automated ways of saying, "Well, SNOMED just added this," or, "LOINC just did this," and, "Here, go look at these because this is the area where changes seem to be more likely to have affected your measure." Rather than having large groups of people around the country looking at new lists of terms or something. I mean, this is not so simple to do, I don't believe, but there should be some level of automated support that can be given to that. And, I do actually feel that's kind of an R&D agenda to come up with that.

Janet Corrigan – National Quality Forum – President & CEO
One thing that may help there, we, at NQF, have a sizable effort underway that is funded by HHS. It's a part of our contract with them to develop a much more sophisticated database of performance measures. And, it will be a federated database that reaches out to the steward sites to get the most recent specifications that are being used, but it will also have a user friendly interface to identify types of measures. And, I can see in the future that there could be a way to perhaps tag measures by the particular terminologies or vocabularies that they use.

It might be a way then, if you wanted to get out to all measures, the measure owners that have measures that you've SNOMED and there's a critical change, it would be a way you could access the database to find out who they are and send a message out to them. But, we are now in the process of getting that system in place.

Karen Kmetik – AMA – Director Clinical Performance Evaluation
That seems like that would certainly be very helpful in this. I was really thinking about the notion of saying, "Okay, these 25 codes are relevant to this measure today, and based on the update to SNOMED, this is a measure that needs to be reviewed," as opposed to this other measure that has 25 codes, but it's from another part of the vocabulary or something else happened and therefore there isn't something that's a significant change there.

Sharon Sprenger – The Joint Commission – Project Director
… that would be really helpful and I would just have to tell you now you cannot underestimate the time it takes to maintain measures. And, it's a full-time job for us at the Joint Commission and we actually release twice a year updates to our technical specifications. And so for example, just using ICD-9-CM as an example, we actually start watching when they're kind of prereleased in June and then we now manually have to go looking at all the code tables we have to see the impact. And, then using data out of UB-04, we have to watch every time NUBC makes a change to see how that impacts.

So, you were right. If there was a way in the future to automate but that at the same time to let every developer who's using that know, that would be a really wonderful thing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Floyd.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
There's one quick caveat to your comment, Betsy, about to test if all the codes are current in LOINC. Sometimes the measure's looking and to look back, did something happen within the last ten years or—

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes, no. I agree. You would have to have a much more sophisticated representation of the measure, which I hope we have so we know we're looking this over ten years. But, no, that would be something. And, Stuart has a lot of experience with designing how we're going to maintain the PubMed MEDLINE database based on greater specificity or some level of change or whatever that's made in the mesh vocabulary because we try to have the database come along. And, it's a nontrivial proposition and of course, we actually indexed those articles and we developed the vocabulary, which we have a bit more of a closed system then you're dealing with here. So, this is a very nontrivial problem, but I basically feel that there has to be a way of incrementally getting to the point where we're much smarter at directing this particular measure developer to this particular measure and this change in saying go take a look.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, other questions or discussion for this panel? Okay, thank you very much. Really appreciate your time here and your testimony. Thank you for participating with us.

Okay, we're going to move now to Task Force discussion, a little bit of a summary of what we've heard here today. Just reviewing some of what we've heard. We heard early on from Doug Fridsma from the ONC about the interoperability framework and had an opportunity to get some clarification about what that is and had some questions on that.

In terms of what we've heard from the federal provider panels, we heard some, for me at least, some of the most interesting comments from Terry Cullen about the needs of the role providers who may not otherwise be considered in terms of this kind of work. As well as the need for international standards coordination particularly around metadata for the vocabularies, as well as keeping the clinicians primary care use cases in mind when promoting and disseminating value sets for other purposes.

Then, we also heard after lunch from the other federal providers of value sets and subsets with a very rich discussion there. I won't even attempt to summarize it. I do have, we'll say, four pages of written notes that I'm going to have to go and wade through to figure out how to summarize the discussion there, and then obviously wrapping up here with the panel on value set governance with a particular focus on performance and quality measures.

So, what takeaways would some of the task force members like to highlight for this? Marc?

Marc Overhage – Regenstrief – Director
Well, I guess one of the questions from the discussion that got surfaced a number of times, I'm not sure what the process is for taking this back to the full committee is this notion of how much are we starting over on things and how much are we moving forward? And, certainly the conversation seem to at least raise the question of whether we need to be sensitive to that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. I think that we'll certainly have, for those of us who are standards committee members, which there are several; we'll have the opportunity to bring that up in our discussion there tomorrow. And, I will certainly include that question or that point in the report out that I'll make tomorrow to the full committee. But, I think that's a great point. Marjorie?

Marjorie Greenberg – NCHS – Chief, C&PHDS
Well, I thought it was really an excellent day and I thank the folks, Judy in particular, for putting it all together. I learned a lot. I think several people have mentioned it. I think we heard in almost every panel, whatever, this tension between if not letting 1,000 flowers bloom, certainly having multiple groups working on value sets so that the value sets meets the need, so that it fits the use. And, that makes sense. Obviously, the people who know the area and have the expertise need to be involved.

And yet, a real cry for coordination and generally the support, it seems, for a registry function that at least would allow people to know where to find things and to have them categorized in standardized ways, etc. But, we all know that there's a leap from that to actually getting more harmonization and agreement. And, I think I heard, also, a desire for that, for more harmonization, more agreement, and for despite all these different actors having parsimony. And, that I think is—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy It's a neat trick. We can do it, right?

Marjorie Greenberg – NCHS – Chief, C&PHDS
They all do fit together in a nontrivial way as just been mentioned and the fact that there really is a shortage of expertise in vocabulary development and maintenance. There are some leaders, obviously, in this area, certainly the National Library of Medicine. But just how much, I don't know, I don't want to use the word power, but you want to give anyone who is managing this registry from the point of view of trying to reduce duplication and of kind of saying the same thing in many different ways and for harmonization.

I didn't really hear any strong suggestions other than we need to do it as to how it can be done without violating the respect for all the different developers. So, I'm not answering this problem, but I'm saying I think that's where it's sort of at right now. There's a lot of agreement up to that point.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, I would say just to respond to your comments here, I would say I also heard very strong agreement with sort of the central themes of needing a centralized coordinator in the federal government with some legal authority and funding. The ability to pursue intergovernmental interagency coordination and to at least fund, if not operate, a central repository or registry for value sets and subsets. And, then I would also agree that there's a dynamic tension between different approaches to achieving parsimony of the approach of harmonization driven through the central authority, Chris's idea of modularity and perhaps

other ways of essentially managing the conflicts that we heard about the different missions of different agencies and the fact that there may be some limits to the central authority of the central authority.

So, in order to manage that, I'm going to suggest that there may be something we can consider as a task force is a recommendation of having perhaps a handful, a small number of pilots where we might seek harmonization approach driven by central authority. For some purposes we might seek to explore the modular approach in other purposes and learn from those pilots. So, what do folks think about us perhaps making a recommendation for piloting a couple of different approaches to resolve those tensions? Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Well, I think pilots are a very good idea. So, I would just separate out a couple of things and just reiterate what other people. So, I certainly heard again, we want one agency that has primary responsibility for this. We'd like one repository for this. We want many people contributing to that repository because there are many, many use cases and we want to be able to accept all of those, accept all of that input. And, so I think that implies that there's at least one owner for the value set.

And, then I think the thing that we could accommodate that would move us towards some convergence is that then organizations though could then, if you will, approve or authorize value sets for specific uses within their organization. So, a single value set could be basically it's owned by one group, but there could be many groups who say, "Oh, we approve that as the value set that we're going to use within our organization or within our authority."

So, for a while, the only kind of pressure, I guess, is that people don't want to do extra work and so they try and reuse things that already exist there. And, the stuff that you're talking about where we try and do something more than that where we're sort of pushing on people to try and get convergence, I think, is maybe a step passed that. But, the first step is to let people use and distinguish the role of sort of approving a value set for use versus the role of owning the value set, which obligates me to maintenance and other parts.

And so there's probably a lot that we could do. If we could get those four steps, I think we would—well two steps in the sense of allowing, well four steps—single agency, single repository within and you know I'm already starting to hypothesize data structures and logical structures for all these. But, a single structure and a single repository, single owner for the value set, but many people who can basically authorize and say, "Within our organization, within this context, this is the value set that we use." And, then it becomes easy for people to see, "Oh, well for gender or for sex, CMS is using this and VA is using this and DoD is that." That starts to create some informal pressure at least to say why do I need to be different than those organizations.

M
… a tipping point.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, Stuart.

Stuart Nelson – NLM – Head, Medical Subject Headings Section

I think the pilots is a very interesting idea, but I think if you're going to talk about pilots, you have to talk about how are you going to decide when you see the results? What are your measures? How are you going to look at it? And what constitutes a full test? To me, unless a pilot goes through a full set of updates of all the vocabularies and so forth, it's not a sufficient test. So, you might want to think about those types of things.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Other comments, observations about today's session, Chris?

Chris Brancato – Deloitte – Manager, Health Information Technology
Yes, hi, Chris Brancato. I have a couple of observations specifically to Doug's presentation and some of the things that concerns or criticisms that were put on the table. I think that Doug tried to relay to us that there are mechanisms and drivers driving ONC to create a process to meet some of the very things that Marjorie so eloquently elaborated, harmonization activities, usable specifications that had been tested and piloted and whatnot. So, the question I pose almost rhetorically for this committee is if not that, what. I think ONC very much needs to hear that feedback from us in recognition of the drivers behind the creation of that model. So, that's one thing.

The other thing, I think I've heard repeatedly both on our testimony on the 28th and then today was an open and deliberative process for development of value sets. What I'm not sure I heard and I think we need to get to is there was a suggestion by Ken about a representative republic model. I think that's great, but we've also heard from the Indian Health Service and SAMHSA that they didn't feel that model was inclusive of them as stakeholders. So, I'm not sure how we get to bringing those, I'd in reticent to call them fringe, but all of the stakeholders into an inclusive process without the 800 pound gorilla's continually coming to the table and representing their point of views without getting the smaller stakeholders to the table in some meaningful fashion.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great, now in terms of your comment on Doug's process presentation, some of the, just to reflect a little bit further on some of the particular feedback that we've heard hear about it is sort of just aiming towards if not that what, but that it's not necessarily that that's a bad end state process but that this is a fundamental redo of what people have been working on that may take some number of years to instantiate. So, I think a better, perhaps, articulation of what to do in the meantime might be something that I think others around the table could agree with.

M
Yes, we do.

M
… exactly ….

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, just comment on expressing my own feeling but it seems like a wonderful process and I'm persuaded by the value of that process. What I see right now is exactly that. I think that we have adopted a series of standards and associated terminologies and there's work to do to make that very coherent in what we're proposing to do. And, I don't see how the new process that's being put in place, how that connects to what we're doing today.

So, as a long-term strategy, I'm very persuaded and think that's a great way to go, but it's almost like we need to do that as a process that runs in parallel for a period of time. And until that's mature enough that we can step off the train we're on onto that different train, we need to know how that tradeoff goes from the new idea and this coherent interoperability framework from sort of the thing where we're at now where we've adopted a set of standards that are not necessarily completely coherent and need to make it work in the short-term absolutely and provide the long-term.

And, if Doug were here, I would ask an additional question, again, which is one of the things that I've noticed is that the enemy of good architecture is urgent need, and Doug seems to be driven by urgent need, which you didn't have a chance to figure out where the pressure's coming from, whether the money's going to run out in some period in time. And, so there's a need to try and make the best use of it this minute or if there's something else that's driving it. But, that's what I worry about is that we're going to let expediency drive and not, in fact, achieve the goal that we hoped to by what's otherwise an elegant approach.

M
One, and I appreciate that, Stan, I really do. The question I have is what's the metaphorical train? Is it HITSP?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Well, I mean, one train is the train we're on now, which is a series of standards that have been adopted that people are expected to implement to achieve meaningful use and incentive money. And, the other train is the interoperability process that he's proposed where we're stepping through things and trying to normalize at a very basic level, data types, value sets, protocols and data exchange standards where we're working now as much more of a unified body from a set of primitives and that the product of those things become the vehicle in the future. That's the thing that we're going to be obligated to use in the future to either achieve incentives or avoid penalties, whichever way you want to—

M
Right.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
That's why I'm thinking of the two trains metaphorically.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes and I would agree violently with Stan. I would add to the train of the adopted standards, the specifications that have been developed and that are used in production in the NHIN of today. So, I would say that's part of the one train.

M
Okay, thanks. I appreciated that.

Janet Corrigan – National Quality Forum – President & CEO
So, a question and some of you will be here to pursue it is really what is the expectation of the switchover point and what happens between now and 2011 versus what may be phased in and maybe put us in a better position in 2013 or 2015. So, I have a question, which Floyd, you may know the answer to this, if the NQF has a job to create a repository of measures, is part of that job to create a repository of the value sets that are in the measures? In which case, we've already started on this task.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
At the moment, the measures in the repository of measures each have with them their respected value sets, but there's no specific repository of value sets. Not that we couldn't do that, but we had two challenges. One was—

Janet Corrigan – National Quality Forum – President & CEO
I'm not suggesting that you should have. I'm just saying that if you have a repository that contains every value set that along one dimension you have a repository of value sets. It's true they're in there with other things, but they're in there, right? I mean, presumably they're findable and among them, I could, for example, say, "Oh my goodness, that's a SNOMED code."

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
In some respects yes, in some respects no. What we currently have in our database is the specification as it's submitted originally for endorsement and we don't currently have all updates. So, any updates to value sets until it comes back for maintenance may not be in the database. They're at their measure stewards site. So, we don't have a current set of all value sets, no.

Janet Corrigan – National Quality Forum – President & CEO
Okay, so this is another thing to consider when figuring out what kind of repository or repositories we would like to have going forward. Clearly, yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, any other summary comments that folks want to make about today's events? Okay, then moving on and planning our future activities, what I'd like to recommend is while we've previously discussed using our info meeting to start discussions about tooling and infrastructure, what I'd like to recommend if Betsy will agree to this, put you on the spot a little bit, is that she and I together will write up a draft recommendation, circulate that based on today and the previous hearing. Circulate that to the group that we will schedule a public call sometime between now and our April meeting. And, so I'll ask Judy to help us with the scheduling of that so that we can review and refine those recommendations so that we can then, for the April meeting of the HIT Standards committee, we can make recommendations based on today and the previous hearing. And, then meanwhile in our own task force meeting in April, we can start to develop a panel for input on tooling and infrastructure alternatives. Is that an acceptable approach going forward for folks? And, Betsy will you work with me on that?

Betsy Humphreys – National Library of Medicine – Deputy Director
Sure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. That's great.

Betsy Humphreys – National Library of Medicine – Deputy Director
Where did we decide—anyway, I have to go back and look at my calendar because I know we moved the April meeting around, didn't we, right, because some of us were going to be—

Judy Sparrow – Office of the National Coordinator – Executive Director
And I don't have my calendar with me so I can't answer you right now.

Betsy Humphreys – National Library of Medicine – Deputy Director
Okay, fine. We'll get back to that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's right, I remember we did—

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes, it's April 1st. We might not be ready by then.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Oh, okay. Well, it's possible then, I do remember, I'm sorry. I had forgotten. We did have to move the April meeting because of a number of different schedule conflicts. So, April will deviate from our usual pattern of being the day before the standards committee meeting.

Judy Sparrow – Office of the National Coordinator – Executive Director
It's earlier.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
It's earlier in the month. With that in mind, one alternative we could consider would be to make April a teleconference and Web meeting to discuss—

M
....

W
What is the …?

W
No, not yet.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Oh, okay.

M
….

W
Yes, I did.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So, we don't have a date in April yet. I thought it had been set and I just didn't remember. Well, what I'd like to ask for consideration is how do folks feel then about making April a teleconference and Web meeting only, virtual meeting, in which we would discuss and refine our recommendations on this thread of activity and then perhaps even put off until May our first hearing on tooling and infrastructure. Is that too much of a delay on the infrastructure or would that be actually perhaps a good plan?

Betsy Humphreys – National Library of Medicine – Deputy Director
It sounds good to me and part of it is Doug laid out the framework today but ONC is in the throws of managing review and fairly imminent, I think, award of multiple contracts that relate to some of these steps. And, it seems to me that when you're dealing with the infrastructure issues since I think some of these contracts will relate to infrastructure or methods by which funding might be provided to other people for infrastructure or so forth that it might be very helpful to sort of get some orientation to where the chips fell with the award of those contracts as partial input to the discussion of these other things.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So perhaps then if it turns out that those awards are made, let's just say hypothetically in April, then perhaps—

Betsy Humphreys – National Library of Medicine – Deputy Director
Not unlikely.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Then perhaps we could contemplate scheduling two virtual meetings before our May meeting, then move forward with the plan to have witnesses testify on alternatives for tooling and infrastructure in May, but we would try to schedule basically two conference calls: one to firm up this set of recommendations and another one to understand the lay of the land given the pending contracts of words that would relate to tooling an infrastructure. Is that a reasonable plan? Judy, can you help us to schedule those two calls?

Judy Sparrow – Office of the National Coordinator – Executive Director
I would be delighted.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. But the first one to review and refine recommendations from today and last month, we need to have those done for presentation, I think, to the Standards Committee in their April meeting. Okay? Is that a plan?

W
…

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
It's the 28th? Yes. ...7th and then the 28th is supposed to be the full committee. So we will have recommendations from the Standards Committee by the 28th and then we'll move forward with a virtual meeting with ONC and perhaps others sometime before our May meeting. Okay? That's a plan. Anything else for the good of the order?

Okay, thank you very much. Now we're ready to move to public comments then.

Judy Sparrow – Office of the National Coordinator – Executive Director
This is the portion of the meeting, I invite members of the public in the room, if you'd like to make a comment, please step forward to the microphone. And on the telephone, if you're already on the phone and you wish to speak, hit *1. And if you're on the Web and wish to dial in, it's 1-877-705-2976. Please state your name, organization and there is a three minute time limit.

Allison Viola – AHIMA – Director of Federal Regulations
My name is Allison Viola from the American Health Information Management Association. On behalf of the AHIMA, I would just like to highlight that in 2007, AHIMA and the American Medical Informatics Association, fully cognizant of the role healthcare terminologies and classifications play in the foundation, integrity and interoperability of healthcare information formed an expert task force to study these issues. The task force was charged to develop recommendations to help establish a process to meet the need for healthcare terminologies and classifications overall strategy.

We recognize the need of the leadership role taken by HHS NLM with regard to the importance of terminologies and classifications, but suggested more needed to be done if the U.S. was to achieve its goal for EHR implementation. The following recommendations were developed in a white paper and I

would like to highlight those for you: Create a publicly funded research and development project; secure funding for the planning and development of a centralized authority; develop a governance model and commit to the adoption of sound principles for the operation of a terminology and classification standards development organization. And I have copies for all of the committee members as well as the full white papers for Betsy and Jamie. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
There are no comments on the phone, so I will turn it back to Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
If there are no other public comments here in the room or on the phone, then we're ready to close this meeting. Okay, we do have a comment on the phone.

Dr. Daniel Ruben – Stanford University – Radiologist & Biomedical Informatics
Can you hear me?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, we can.

Dr. Daniel Ruben – Stanford University – Radiologist & Biomedical Informatics
Very good. Thank you for this opportunity to comment. My name is Dr. Daniel Ruben and I am a radiologist and biomedical informatics researcher at Stanford University. I'm calling today as chairman of the RadLex Steering Committee of the Radiological Society of North America to encourage the members of the HIT Standards Committee and its Vocabulary Task Force to consider RadLex as the vocabulary standard for radiology. RadLex is an active, curated reference terminology for the domain of radiology, which includes over 30,000 terms describing imaging studies designed to unify and supplement non-radiology lexicons and standards such as SNOMED CT described in this HECON, as well as the DICOM standard for imaging. It is currently the only vocabulary specifically designed to comprehensively cover imaging information, which is a critical component of the medical record.

RadLex is supposed by the Radiological Society of North America, the American College of Radiology, and over 30 other radiology professional and standards organizations for radiology terminology. It has also been adopted by numerous imaging system providers and radiology system vendors. RadLex is receiving active federal support, including from the National Institute of Biomedical Imaging and Bio Engineering, and the National Cancer Institute. RadLex has also been designated as silver level compliant for value sets by the Vocabulary Common Data Elements working group of NIH's Cancer Biomedical Informatics Grid, also called CaBIG initiative.

What's important about RadLex is it adopts an open development process. The transparent and collaborative development for RadLex has been validated in review conducted by NIH and CaBIG project and features ongoing communication with the community of adopters of the terminology. Feedback is obtained through public forums and online distribution sites, and change requests are vetted through relevant specialty lexicon development committees, representatives from numerous organizations both within and outside of radiology.

To conclude, just as ONC has recognized LOINC as the vocabulary standard for lab observations, I strongly encourage the same recognition of RadLex for radiology reporting. After all, radiology reports comprise a crucial component of electronic patient records. The RadLex Steering Committee and the American College of Radiology's IT and Informatics Committee would actively support you in this effort. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Dr. Ruben. I believe we have one more commenter on the telephone.

M

My name is … and I'm consultant working at the Centers for Disease Control on the freelance team. One comment is regarding the intrinsic values, which is really made stronger relationships between the concepts and the SDO vocabulary. So for those kinds of value sets it would be useful to engage SDO in those … so that the user and the SDOs would both benefit in the development and maintenance of those value sets.

Second comment is related to the HL7 comment terminology services, it would be useful for the implementers if HL7 CTS and IA…profiled, they both could collaborate much more closely so that there won't be two silos going on so they implement a common terminology ….

Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Now if there are no other comments, either in the room or on the phone, I want to thank everybody here, both our panelists and the task force members for participating here today. I think this was a great discussion and look forward to our next steps. Thanks, everybody.